



1/64

STEP : 0.050° CNT TIME: 1.000 SEC.  
RANGE: 2.00 - 40.00 (DEG) CONT. SCAN RATE : 3.00 DEG/MIN.

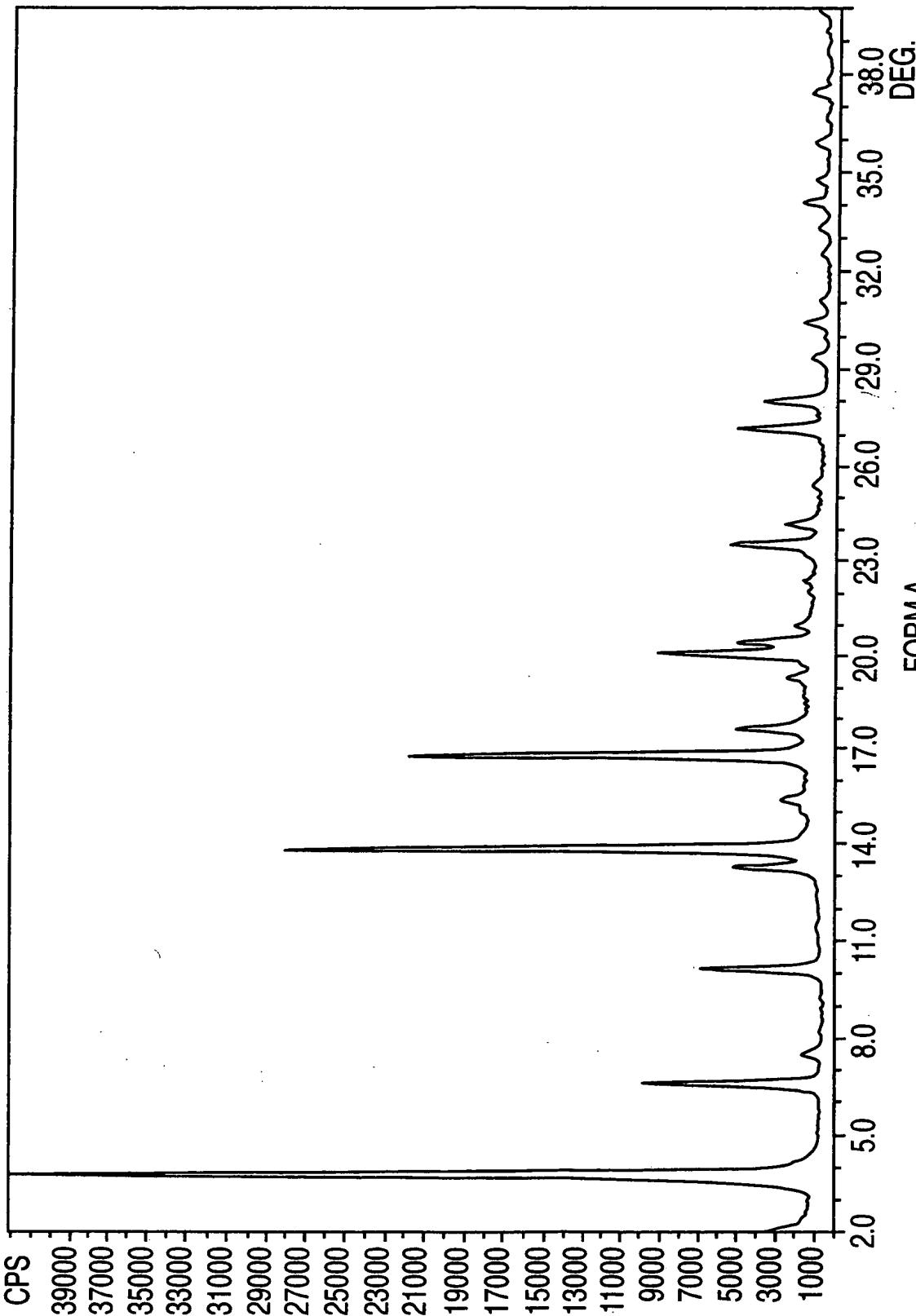
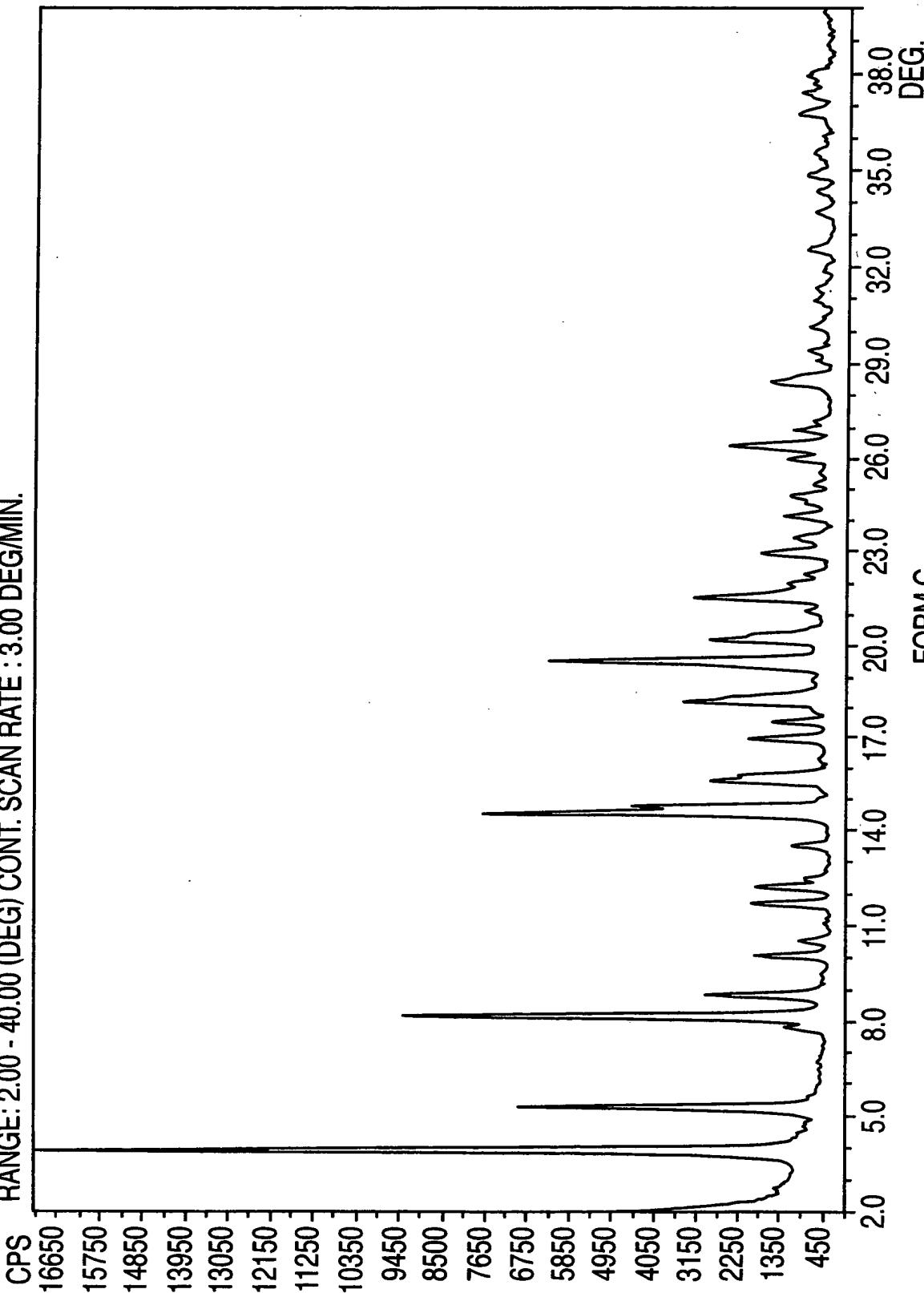


FIG. 1  
FORM A

⊗

STEP : 0.050° CNT TIME: 1.000 SEC.  
RANGE: 2.00 - 40.00 (DEG) CONT. SCAN RATE : 3.00 DEG/MIN.



FORM C  
FIG. 2

STEP : 0.050° CNT TIME: 1.000 SEC.  
RANGE: 2.00 - 40.00 (DEG) CONT. SCAN RATE : 3.00 DEG/MIN. TEVA

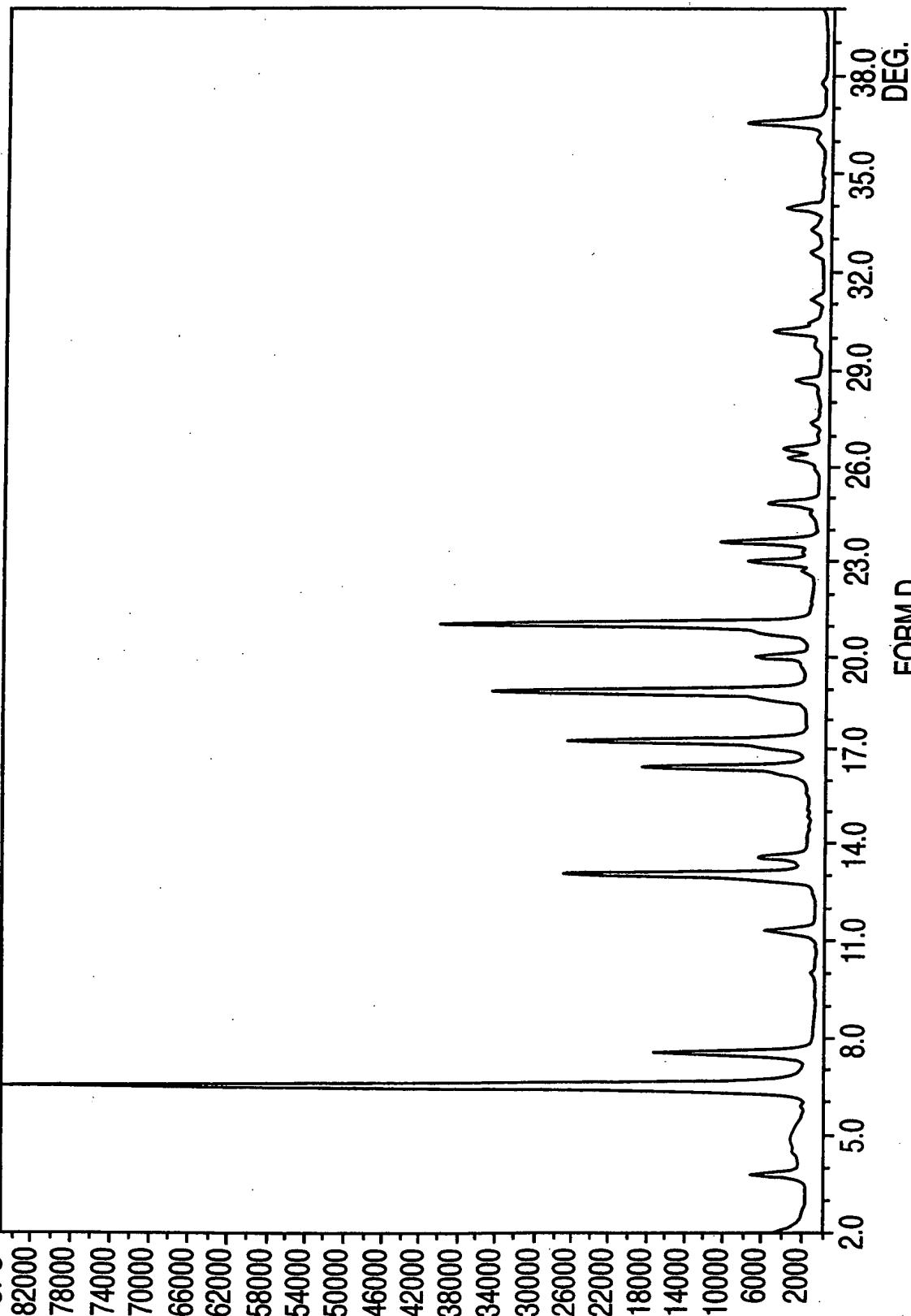


FIG. 3  
FORM D

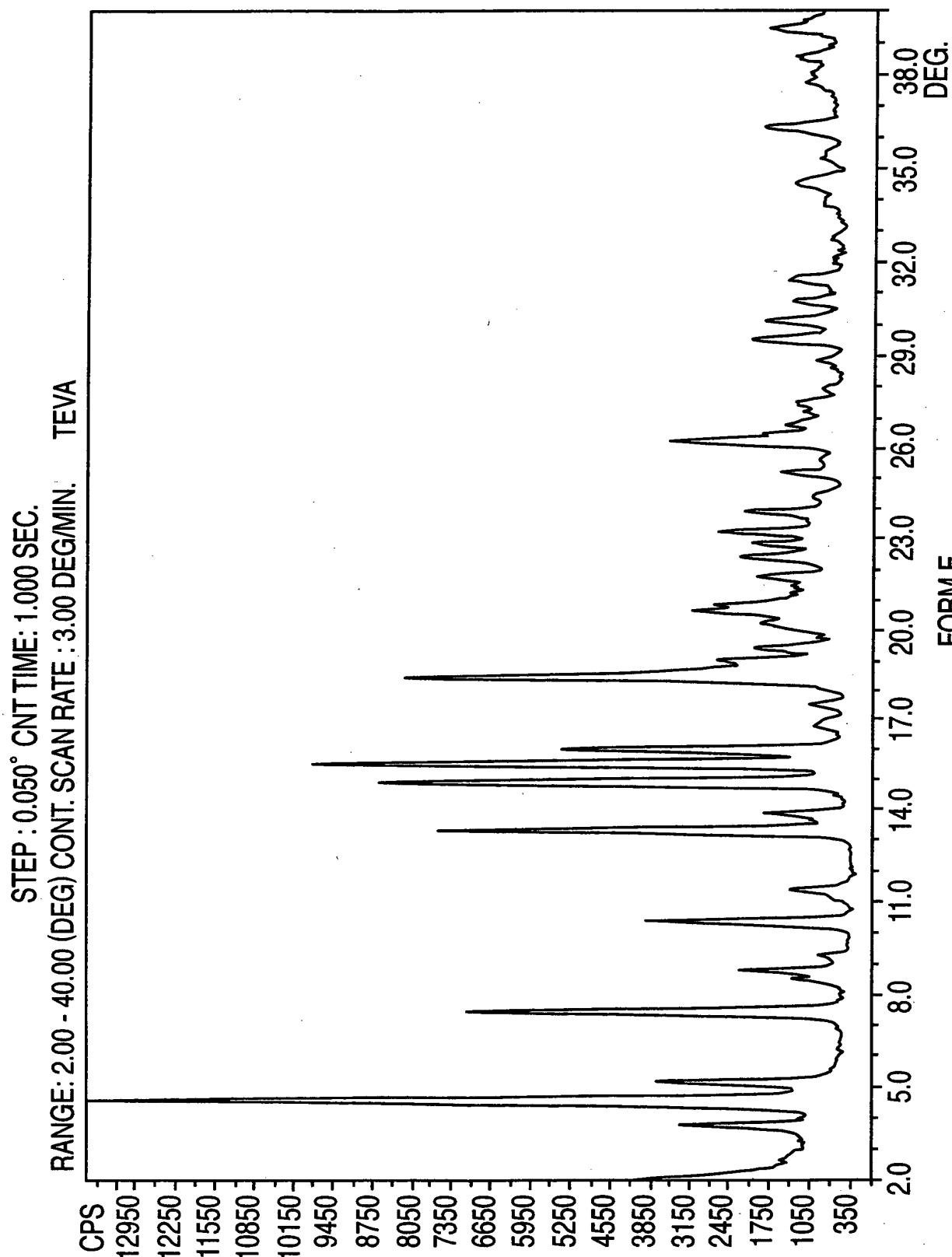


FIG. 4

STEP : 0.05° CNT TIME: 1.000 SEC.  
RANGE: 2.00 - 40.00 (DEG) CONT. SCAN RATE : 3.00 DEG/MIN.

CPS

21000

19800

18600

17400

16200

15000

13800

12600

11400

10200

9000

7800

6600

5400

4200

3000

1800

600

⊕

FIG. 5  
FORM F

DEG.

38.0

35.0

32.0

29.0

26.0

23.0

20.0

17.0

14.0

11.0

8.0

5.0

2.0

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STEP : 0.050° CNT TIME: 1.000 SEC.  
RANGE: 2.00 - 40.00 (DEG) CONT. SCAN RATE : 3.00 DEG/MIN.

⊕

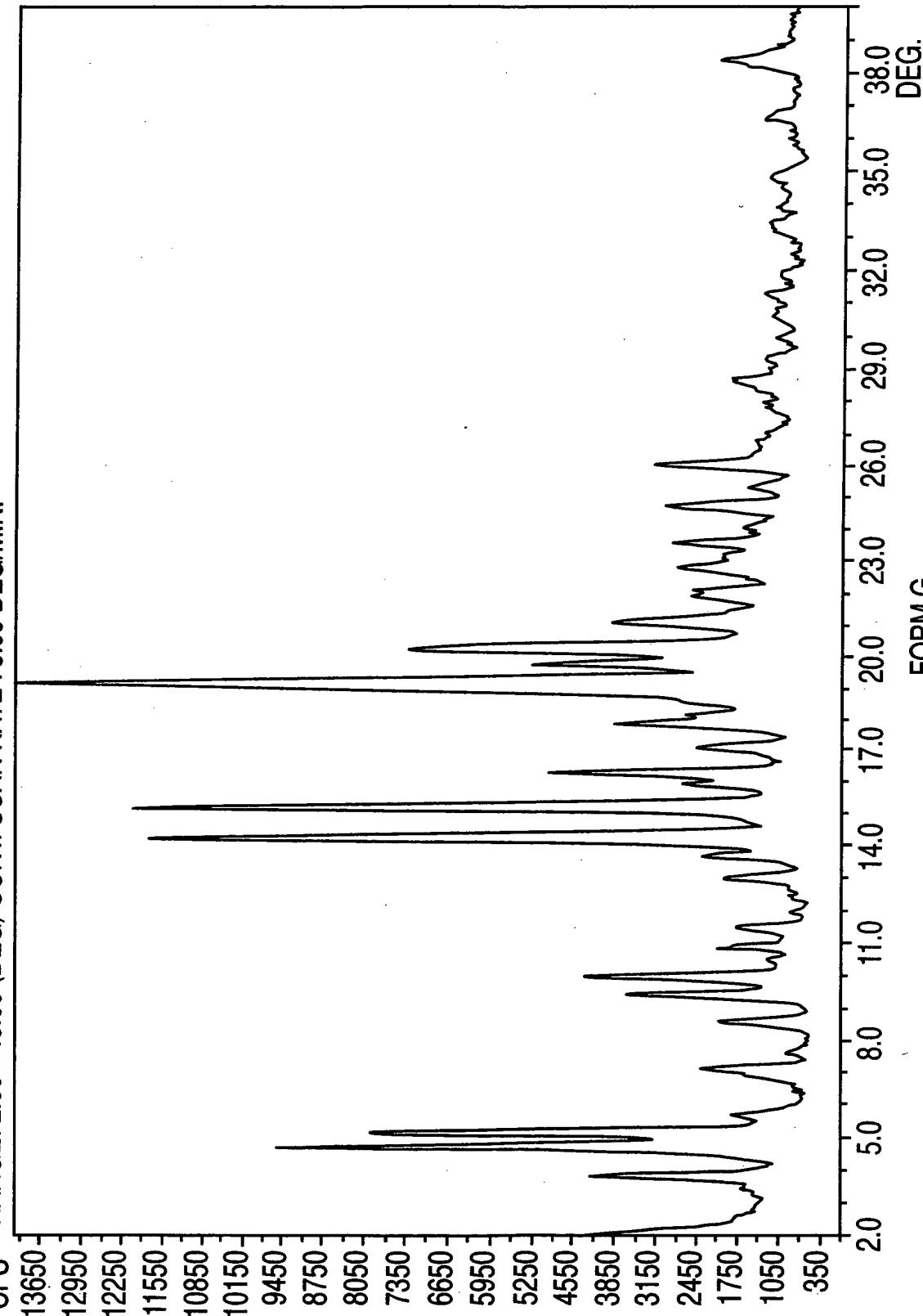


FIG. 6  
FORM G

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STEP : 0.05° CNT TIME: 1.000 SEC.  
RANGE: 2.00 - 40.00 (DEG) CONT. SCAN RATE : 3.00 DEG/MIN. TEVA

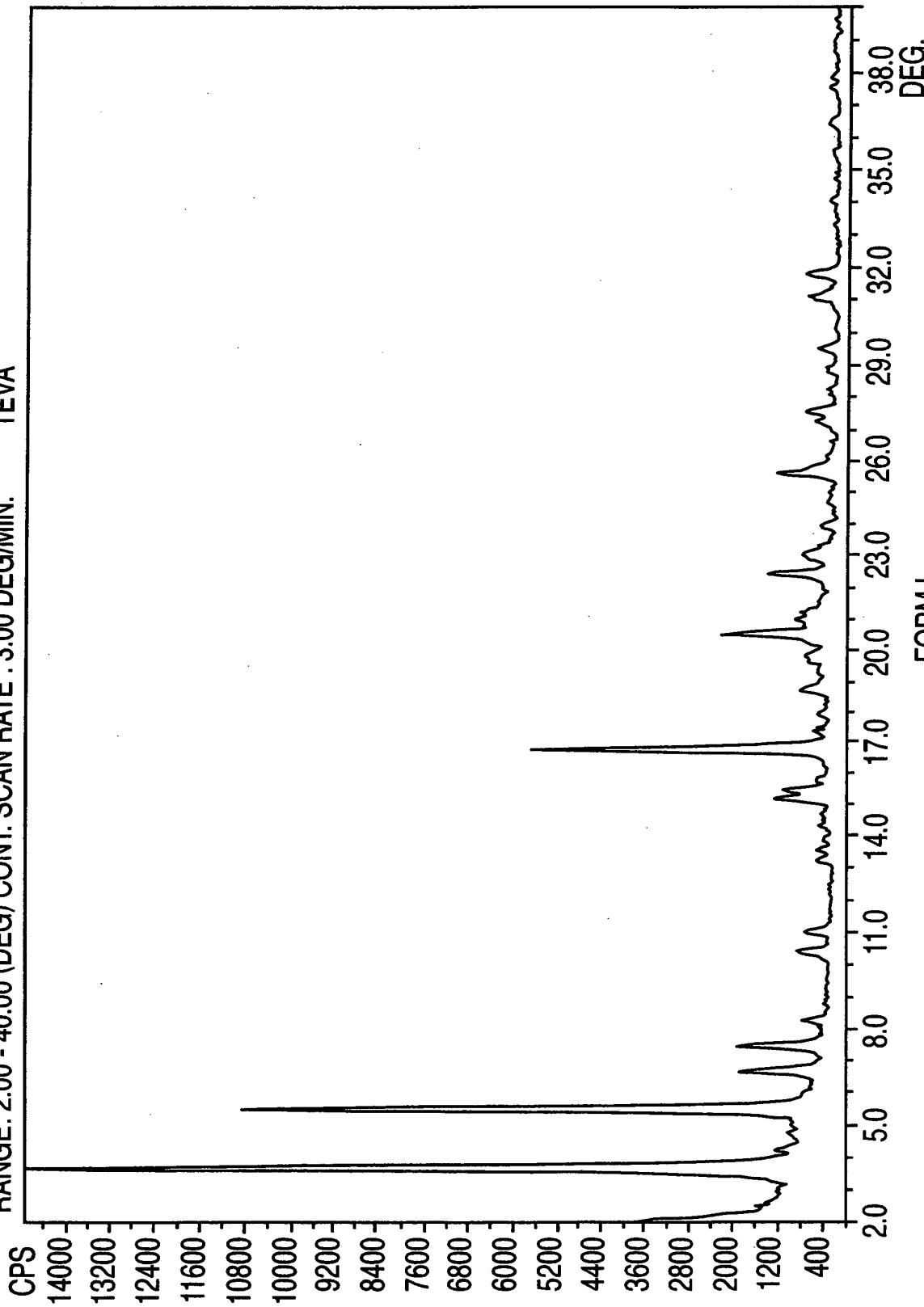


FIG. 7  
FORM I

STEP : 0.050° CNT TIME: 1.000 SEC.  
RANGE: 2.00 - 40.00 (DEG) CONT. SCAN RATE : 3.00 DEG/MIN.

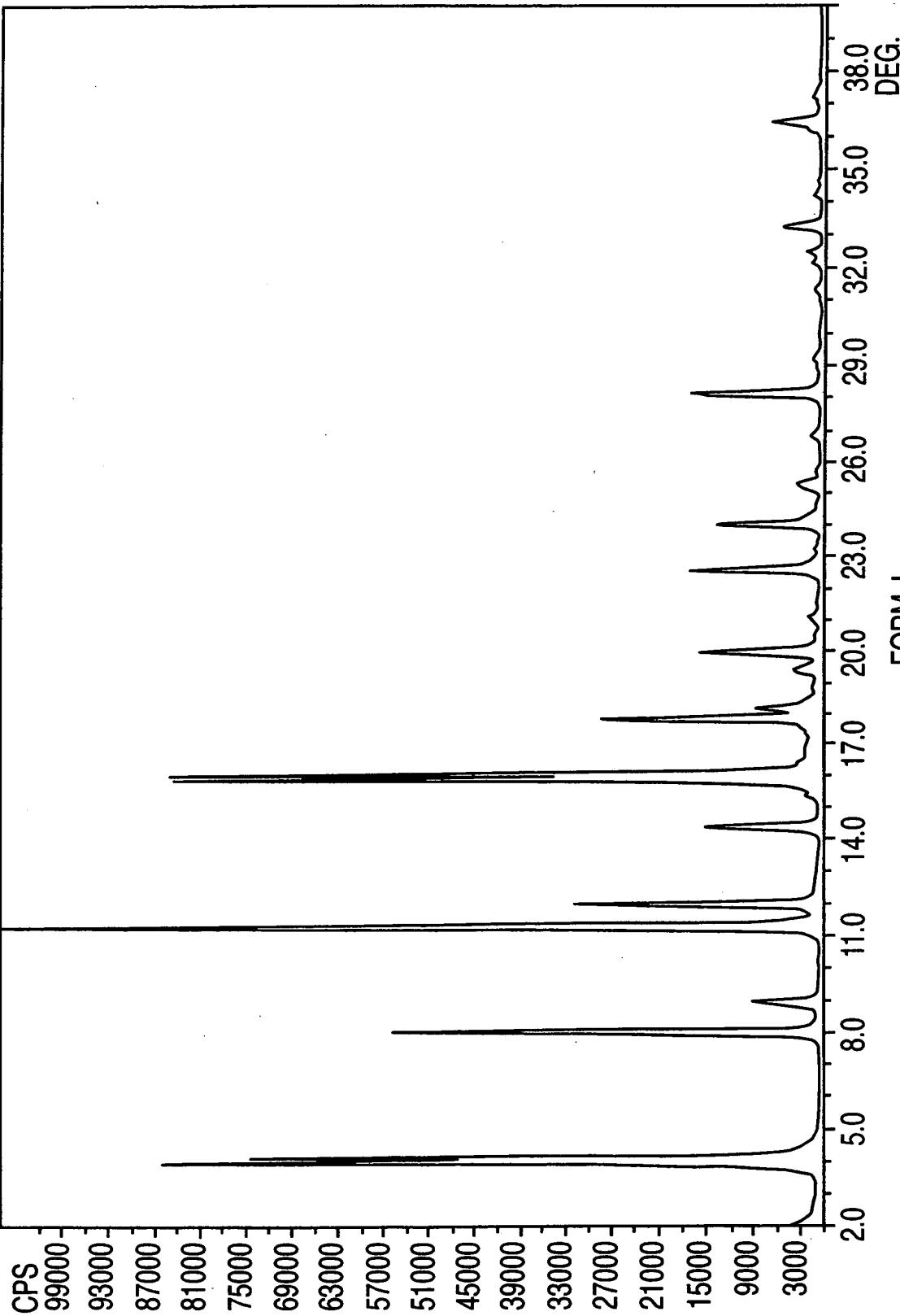
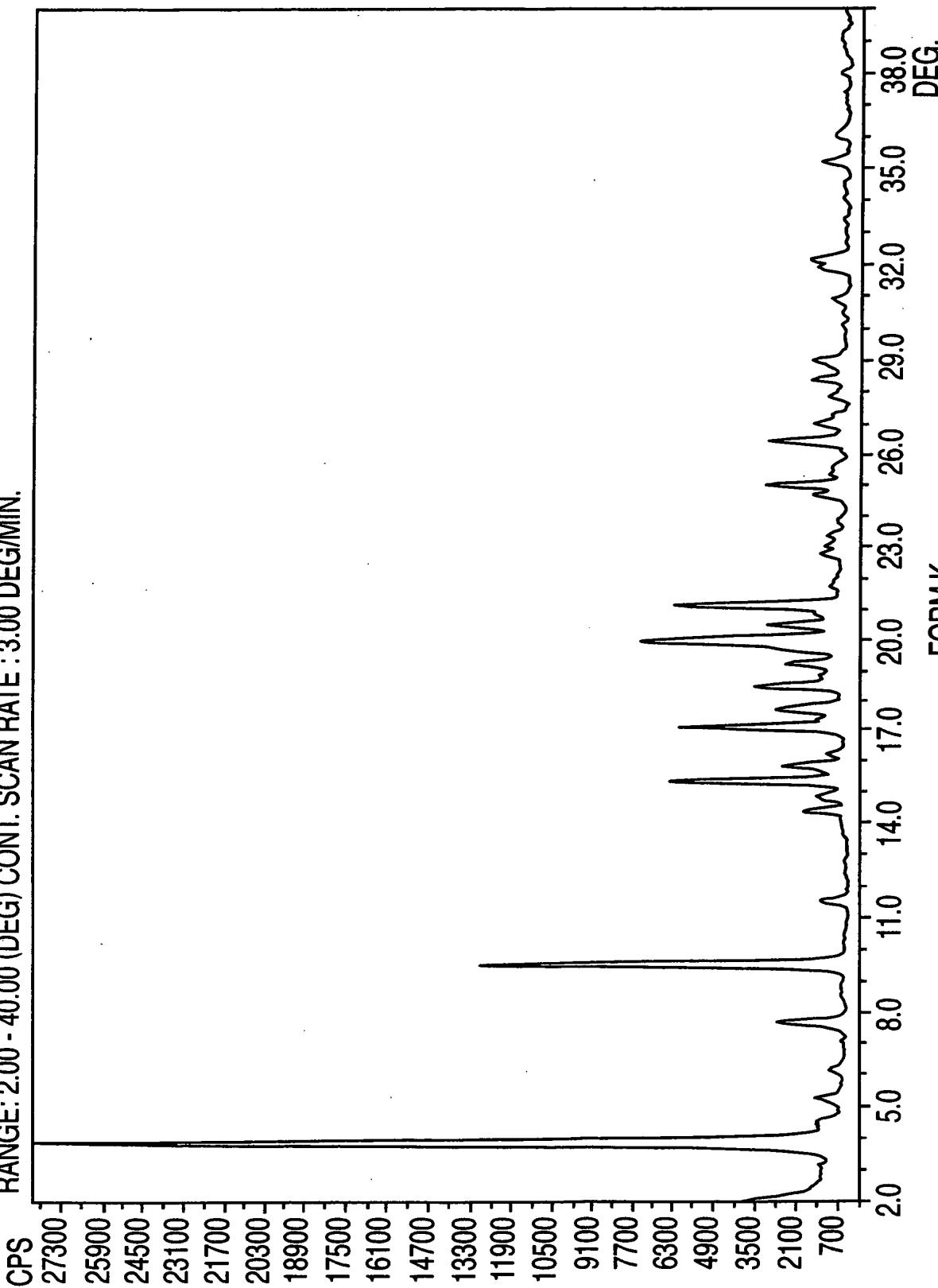


FIG. 8  
FORM J

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STEP : 0.050° CNT TIME: 1.000 SEC.  
RANGE: 2.00 - 40.00 (DEG) CONT. SCAN RATE : 3.00 DEG/MIN.

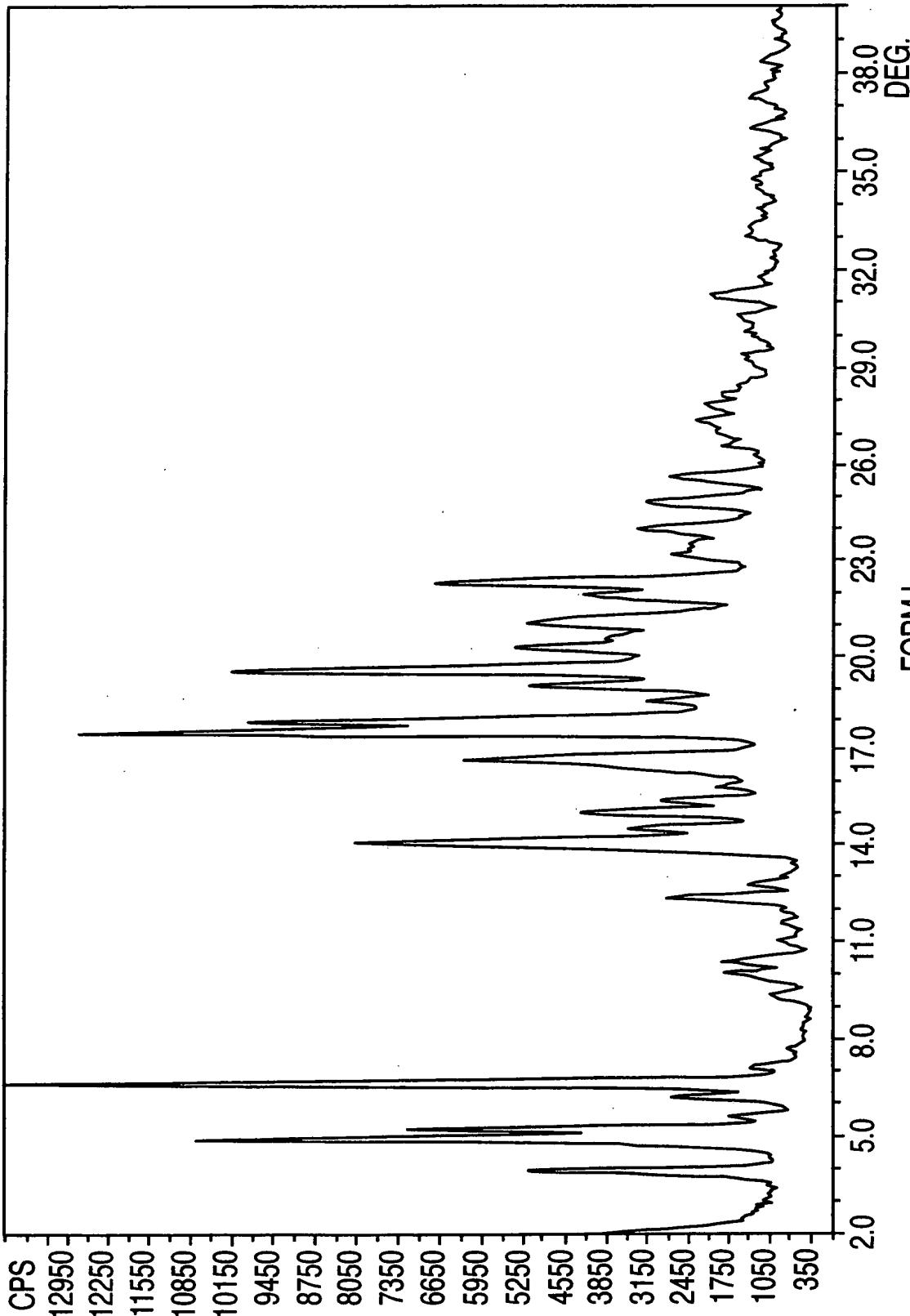


⊕

FIG. 9  
FORM K

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STEP : 0.050° CNT TIME: 1.000 SEC.  
RANGE: 2.00 - 40.00 (DEG) CONT. SCAN RATE : 3.00 DEG/MIN.



⊕

FIG. 10  
FORM L

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⊕

STEP : 0.050° CNT TIME: 1.000 SEC.  
RANGE: 2.00 - 40.00 (DEG) CONT. SCAN RATE : 3.00 DEG/MIN.

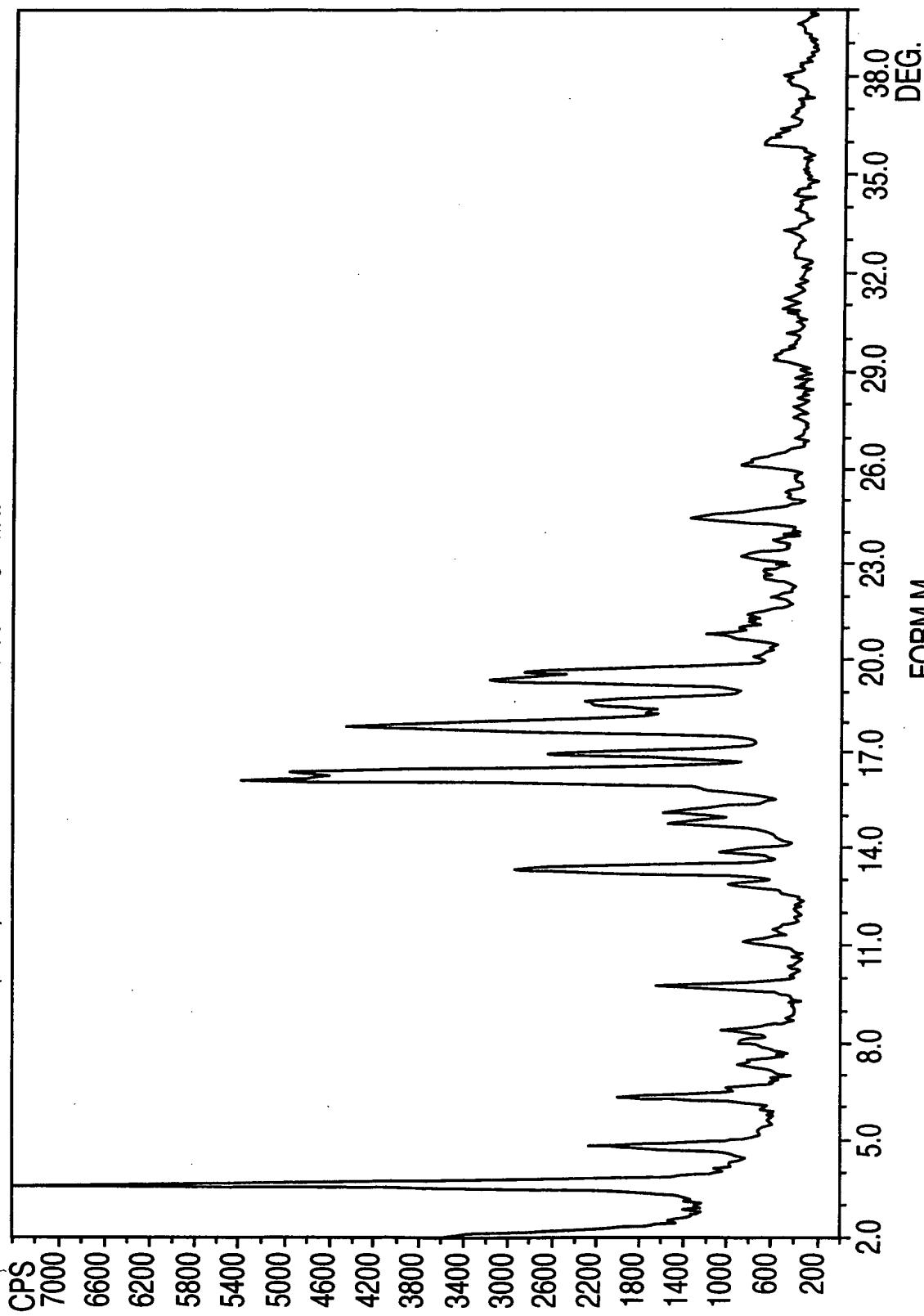


FIG. 11  
FORM M

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STEP : 0.050° CNT TIME: 1.000 SEC.  
RANGE: 2.00 - 40.00 (DEG) CONT. SCAN RATE : 3.00 DEG/MIN.

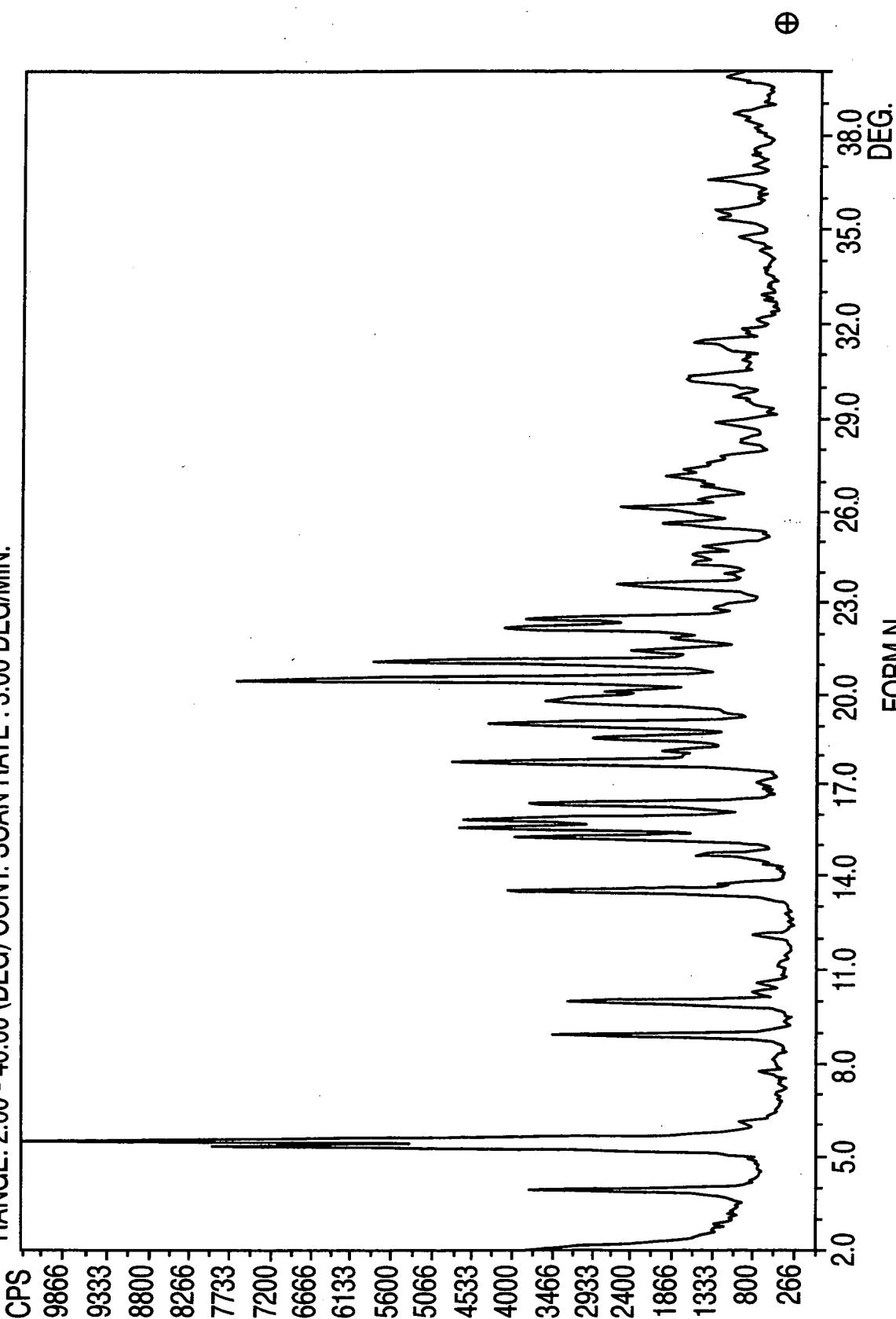


FIG. 12  
FORM N

STEP : 0.050° CNT TIME: 1.000 SEC.  
RANGE: 2.00 - 40.00 (DEG) CONT. SCAN RATE : 3.00 DEG/MIN.

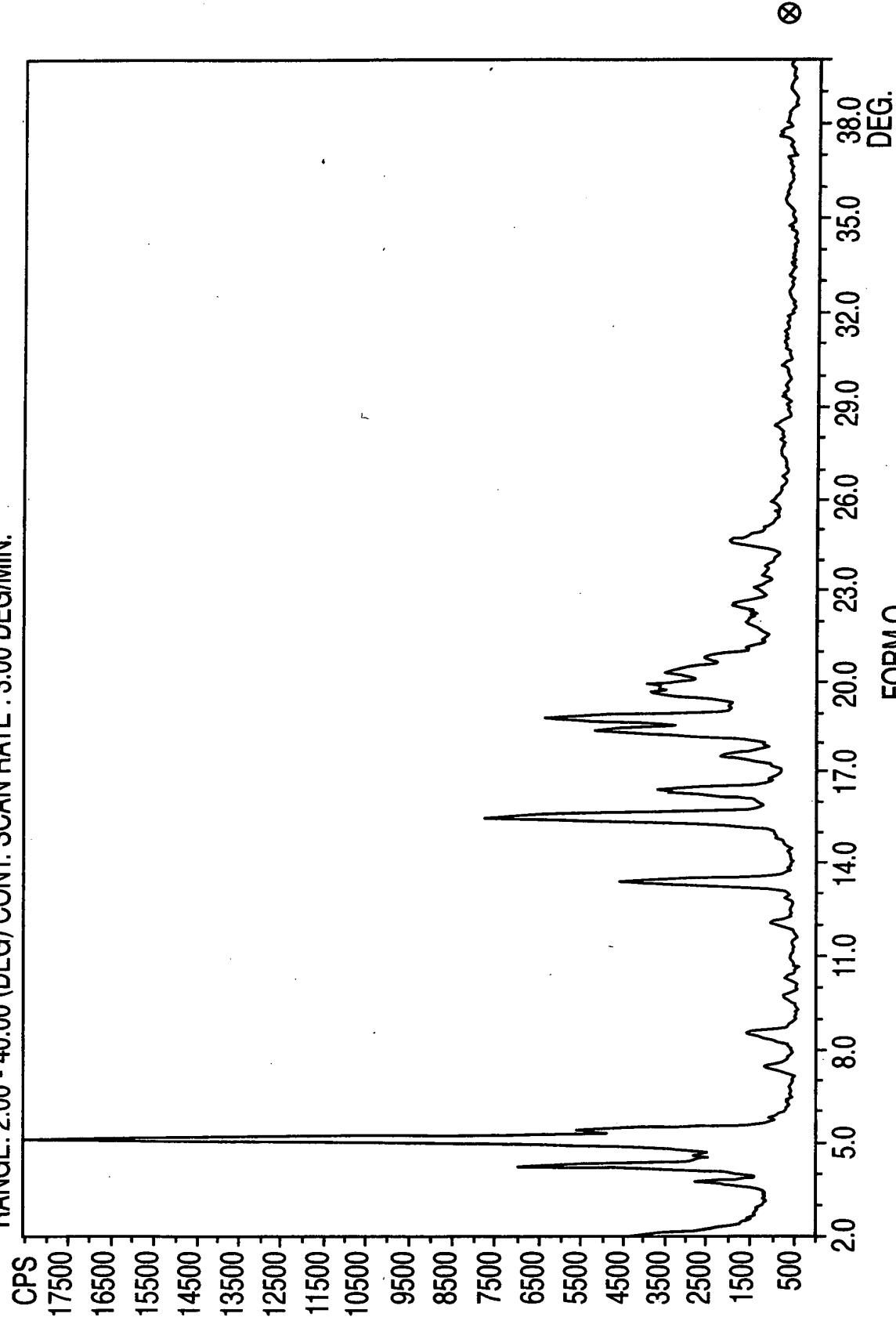


FIG. 13  
FORM O

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STEP : 0.050° CNT TIME: 1.000 SEC.  
RANGE: 2.00 - 40.00 (DEG) CONT. SCAN RATE : 3.00 DEG/MIN.

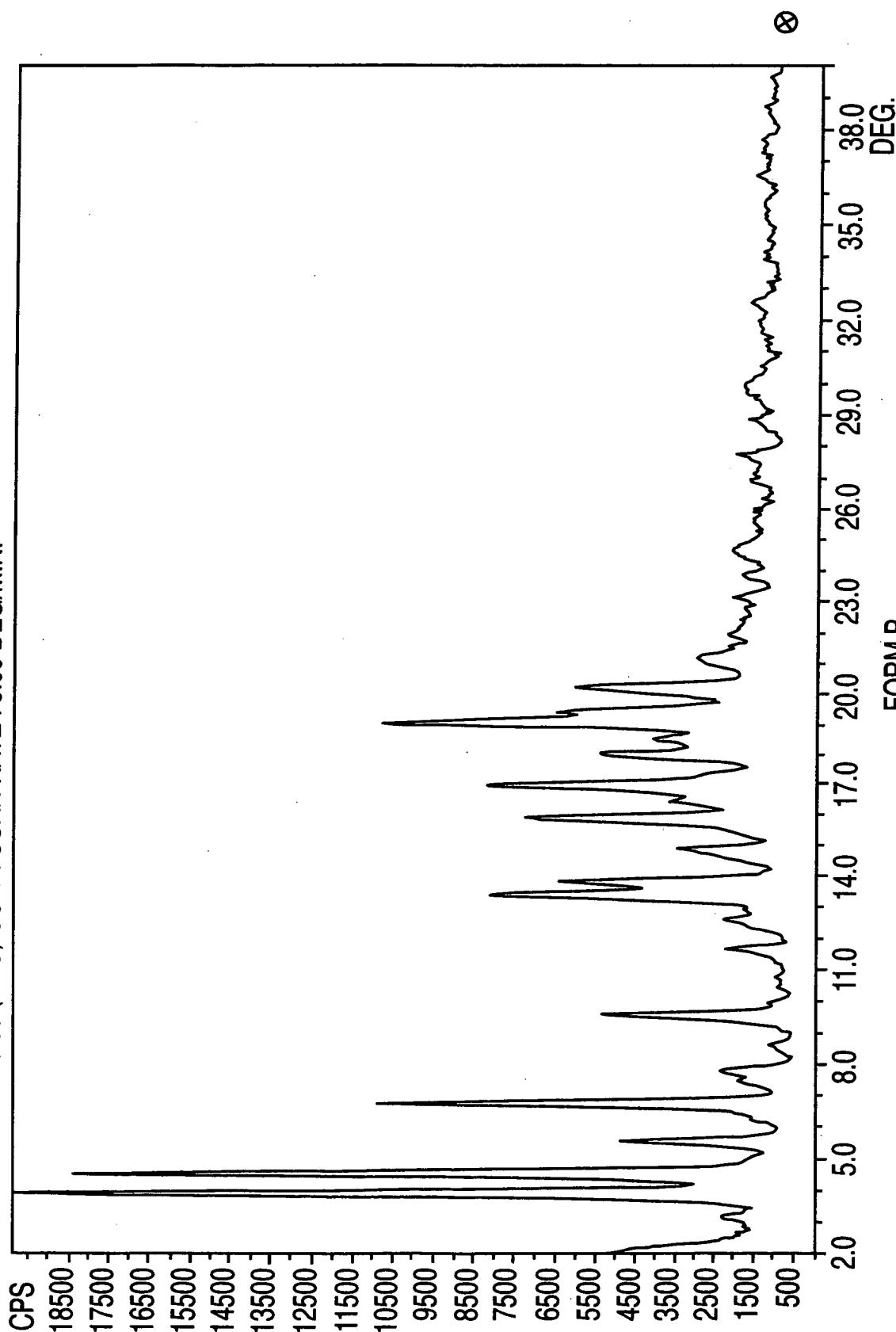


FIG. 14  
FORM P

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⊗

STEP : 0.050° CNT TIME: 1.000 SEC.  
RANGE: 2.00 - 40.00 (DEG) CONT. SCAN RATE : 3.00 DEG/MIN.

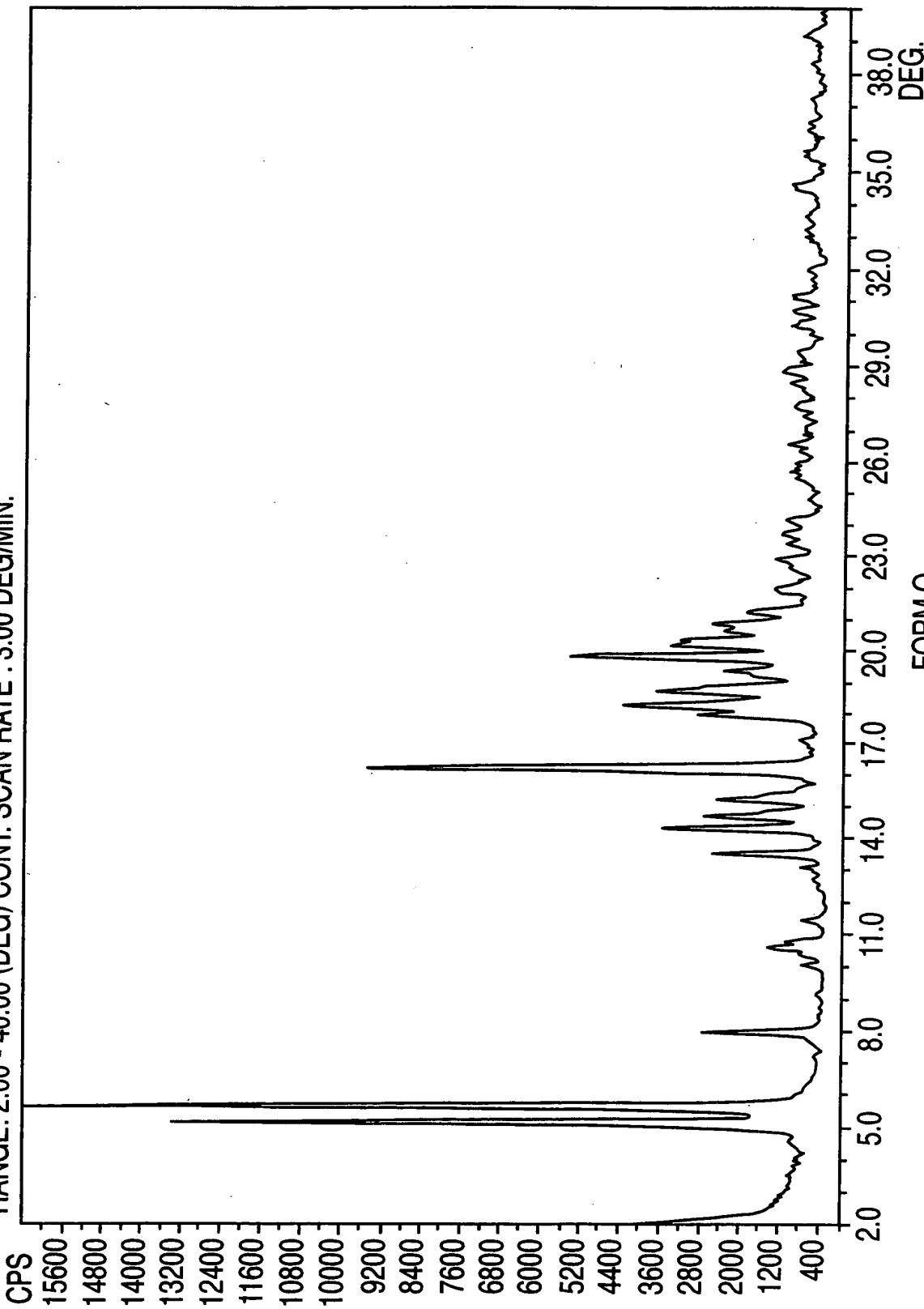


FIG. 15  
FORM Q

⊕

STEP : 0.050° CNT TIME: 1.000 SEC.  
RANGE: 2.00 - 40.00 (DEG) CONT. SCAN RATE : 3.00 DEG/MIN.

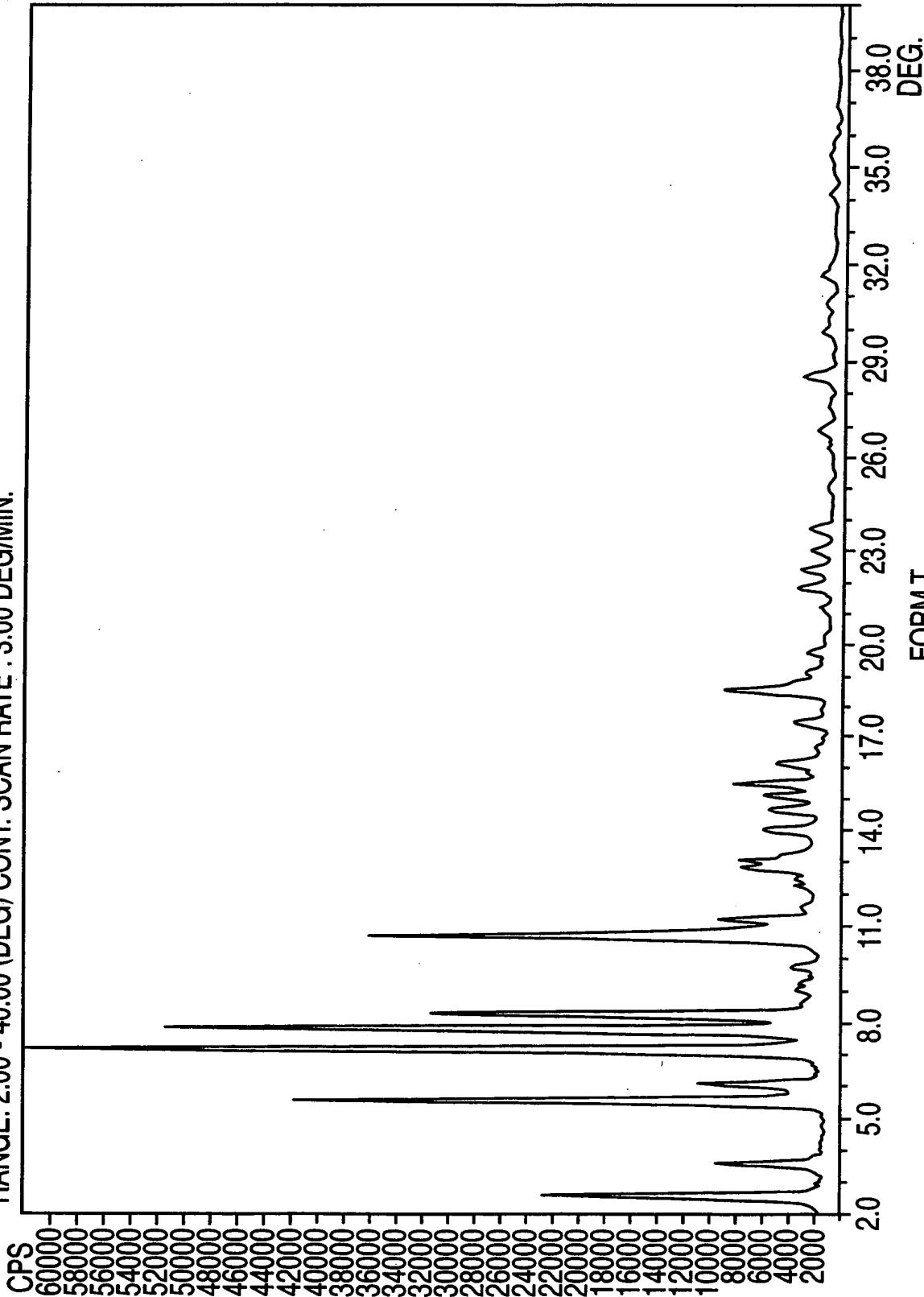


FIG. 16  
FORM T

STEP : 0.050° CNT TIME: 1.000 SEC.  
RANGE: 2.00 - 40.00 (DEG) CONT. SCAN RATE : 3.00 DEG/MIN.

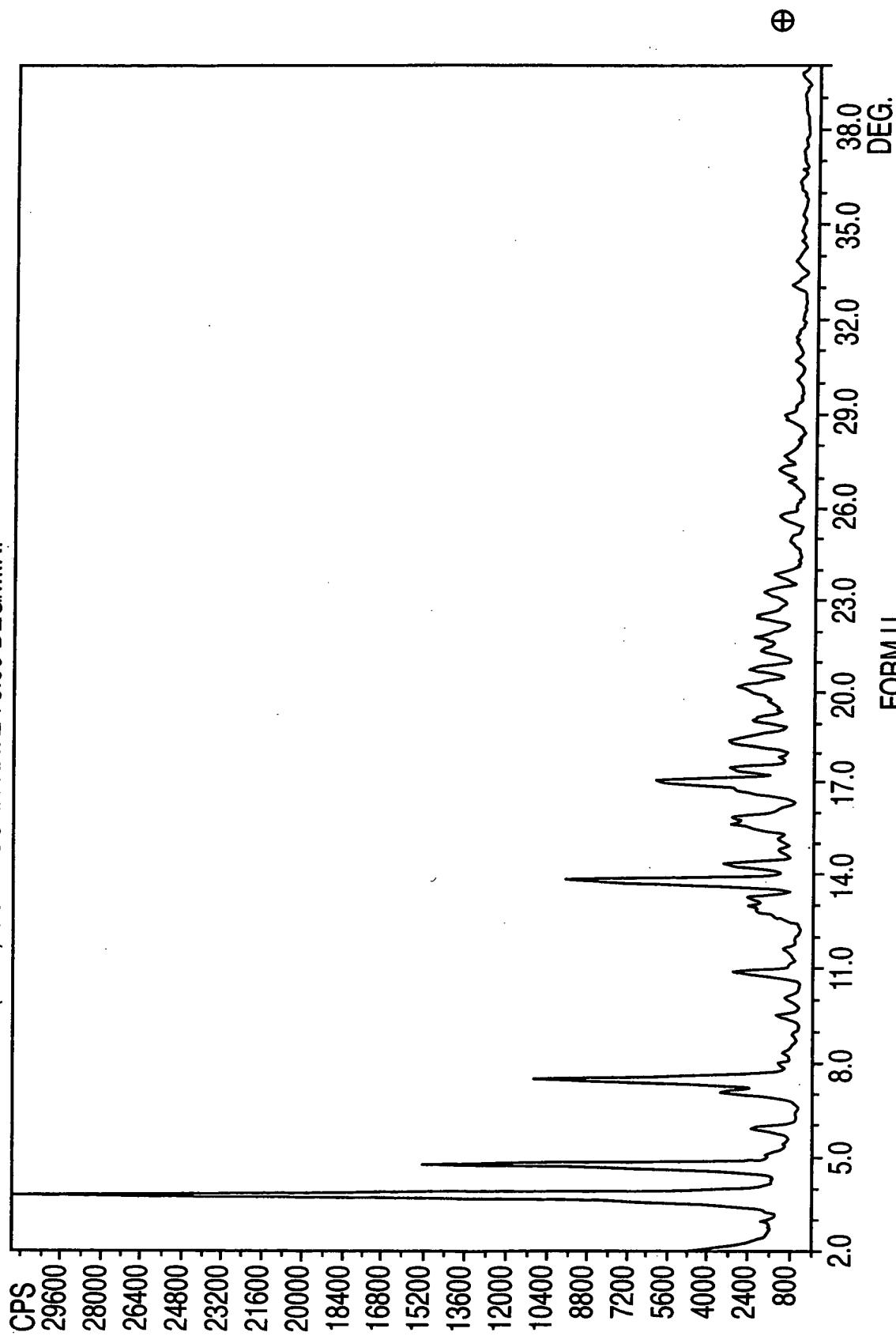
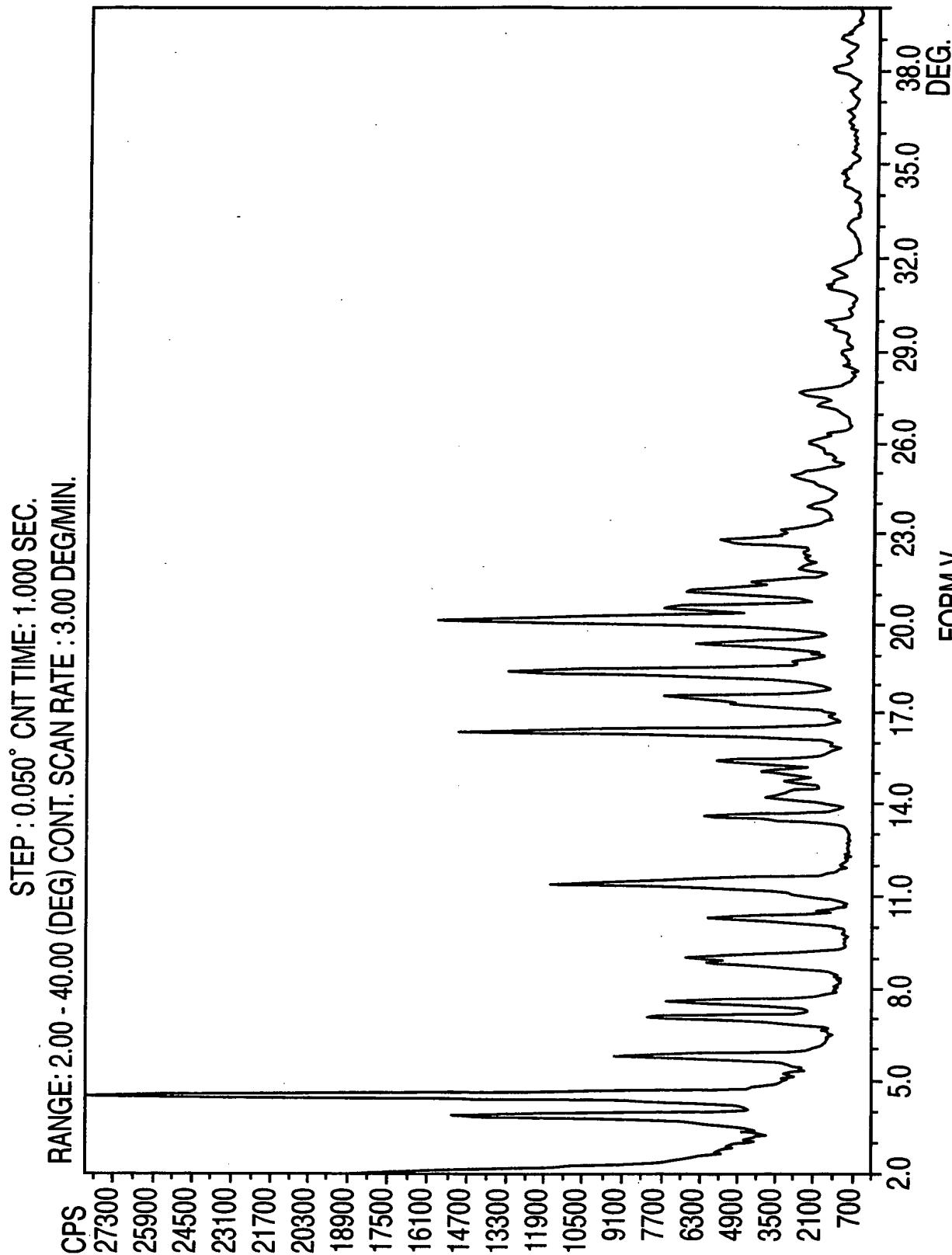


FIG. 17

1



**FIG. 18**

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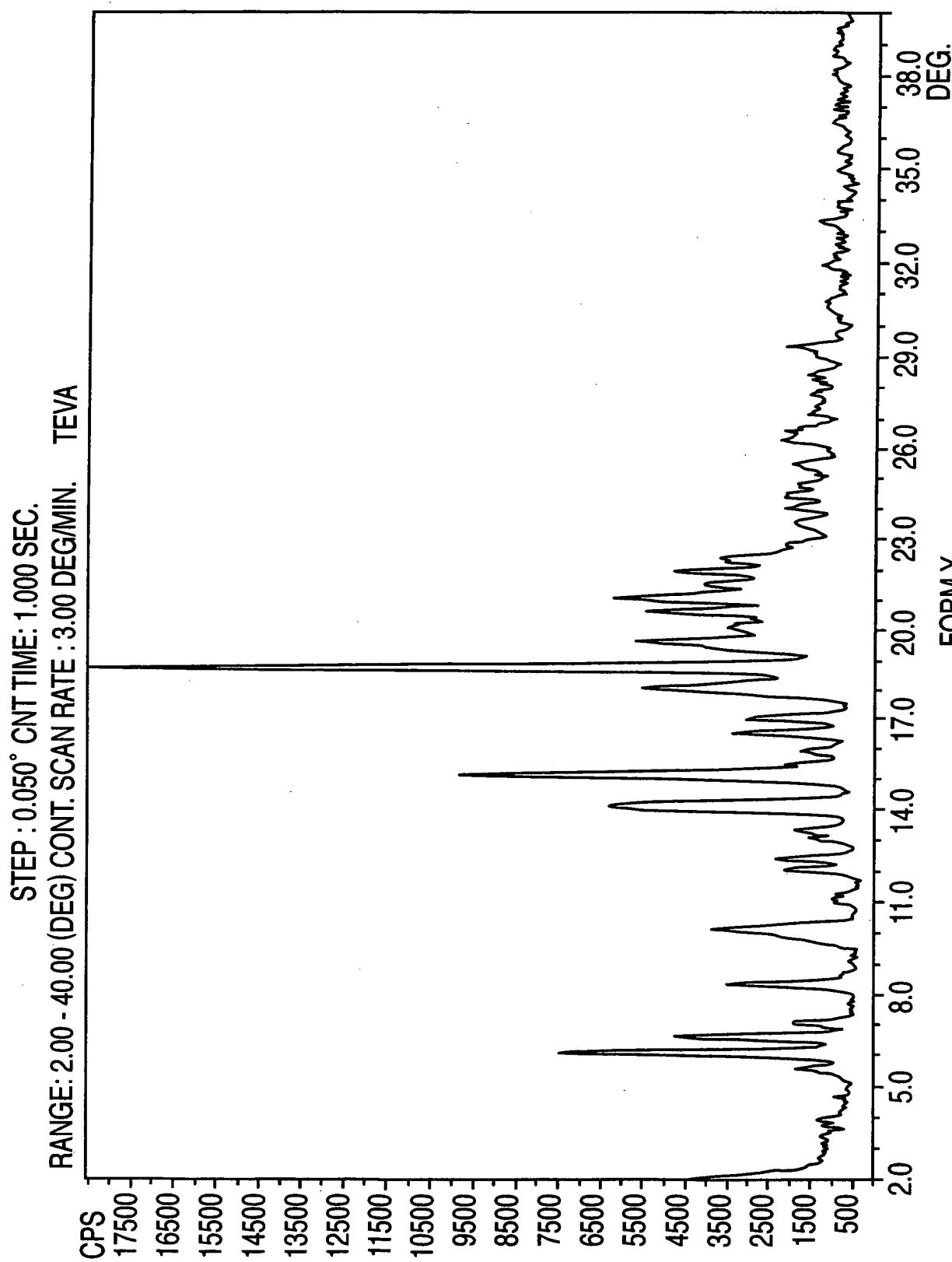
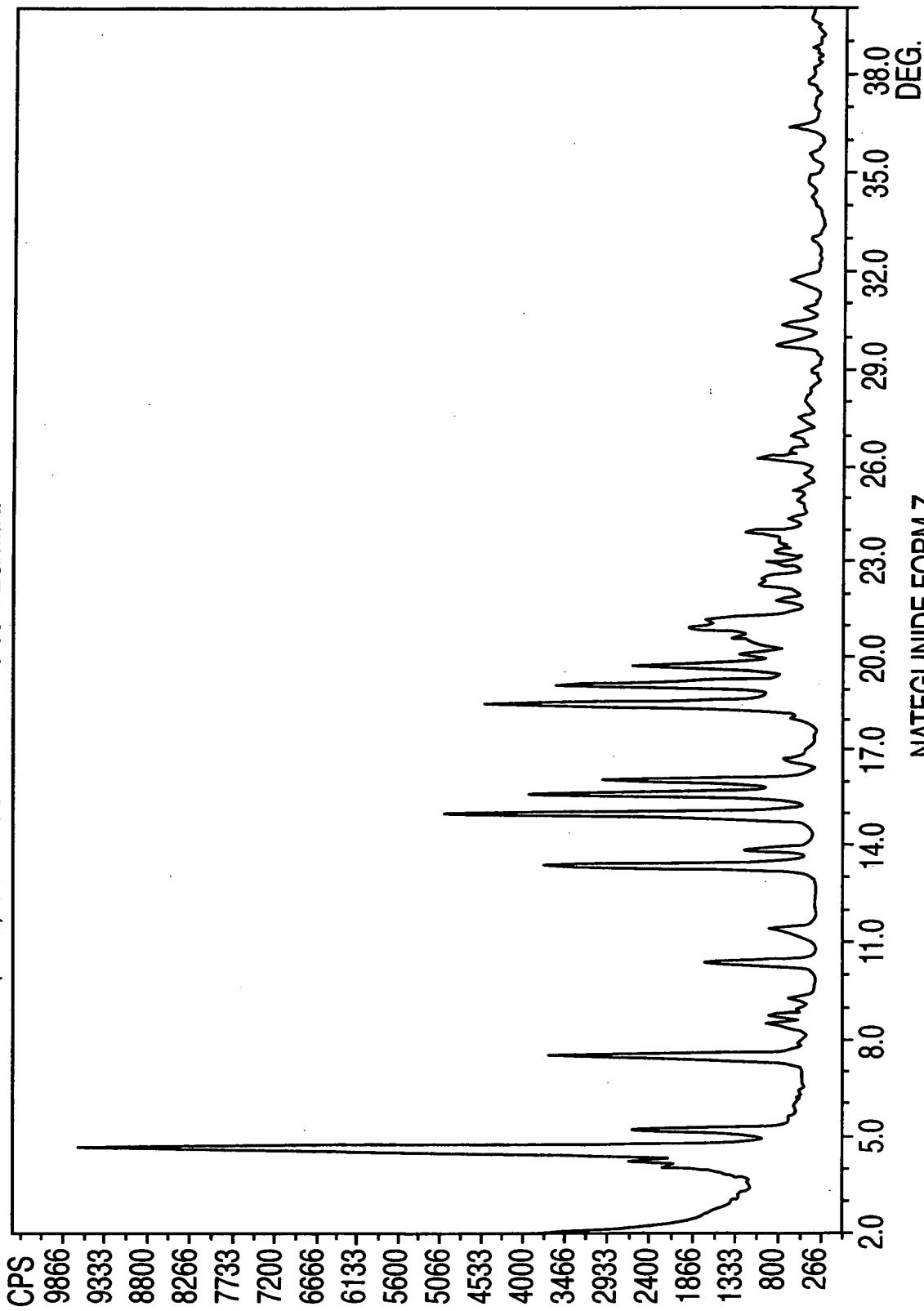


FIG. 19  
FORM Y

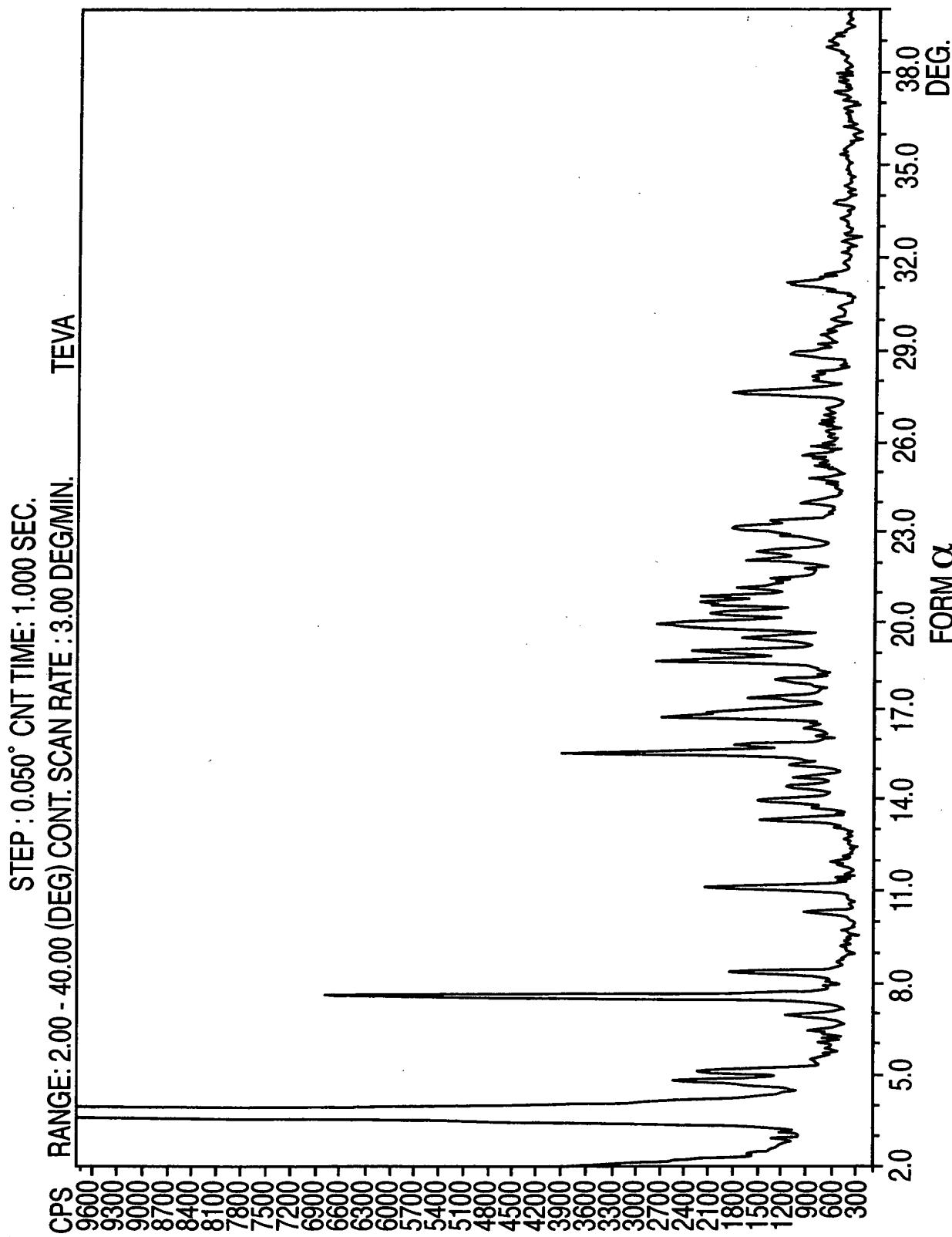
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STEP : 0.050° CNT TIME: 1.000 SEC.  
RANGE: 2.00 - 40.00 (DEG) CONT. SCAN RATE : 3.00 DEG/MIN.



NATEGLINIDE FORM Z  
FIG. 20

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STEP : 0.050° CNT TIME: 1.000 SEC.  
RANGE: 2.00 - 40.00 (DEG) CONT. SCAN RATE : 3.00 DEG/MIN. TEVA

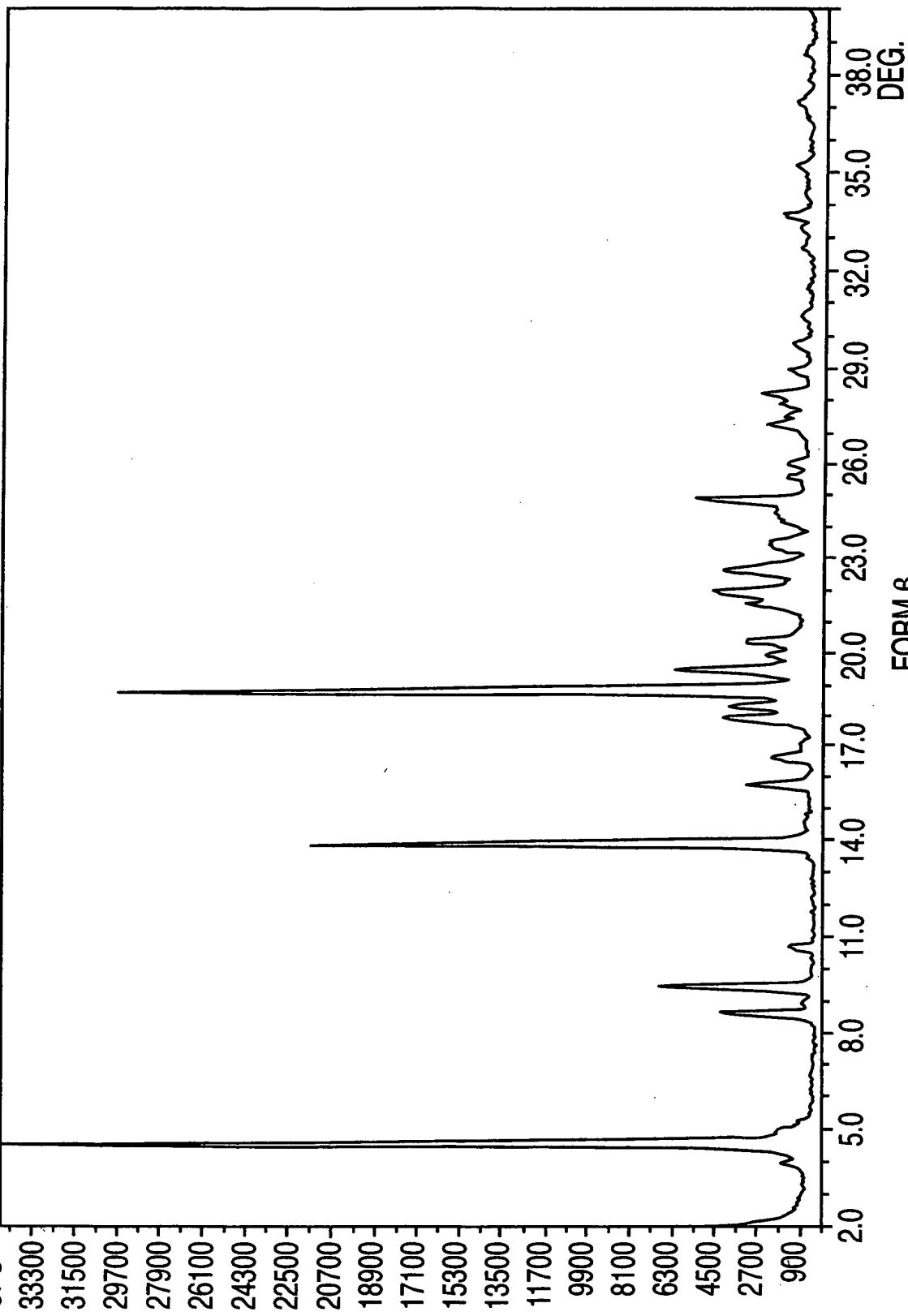
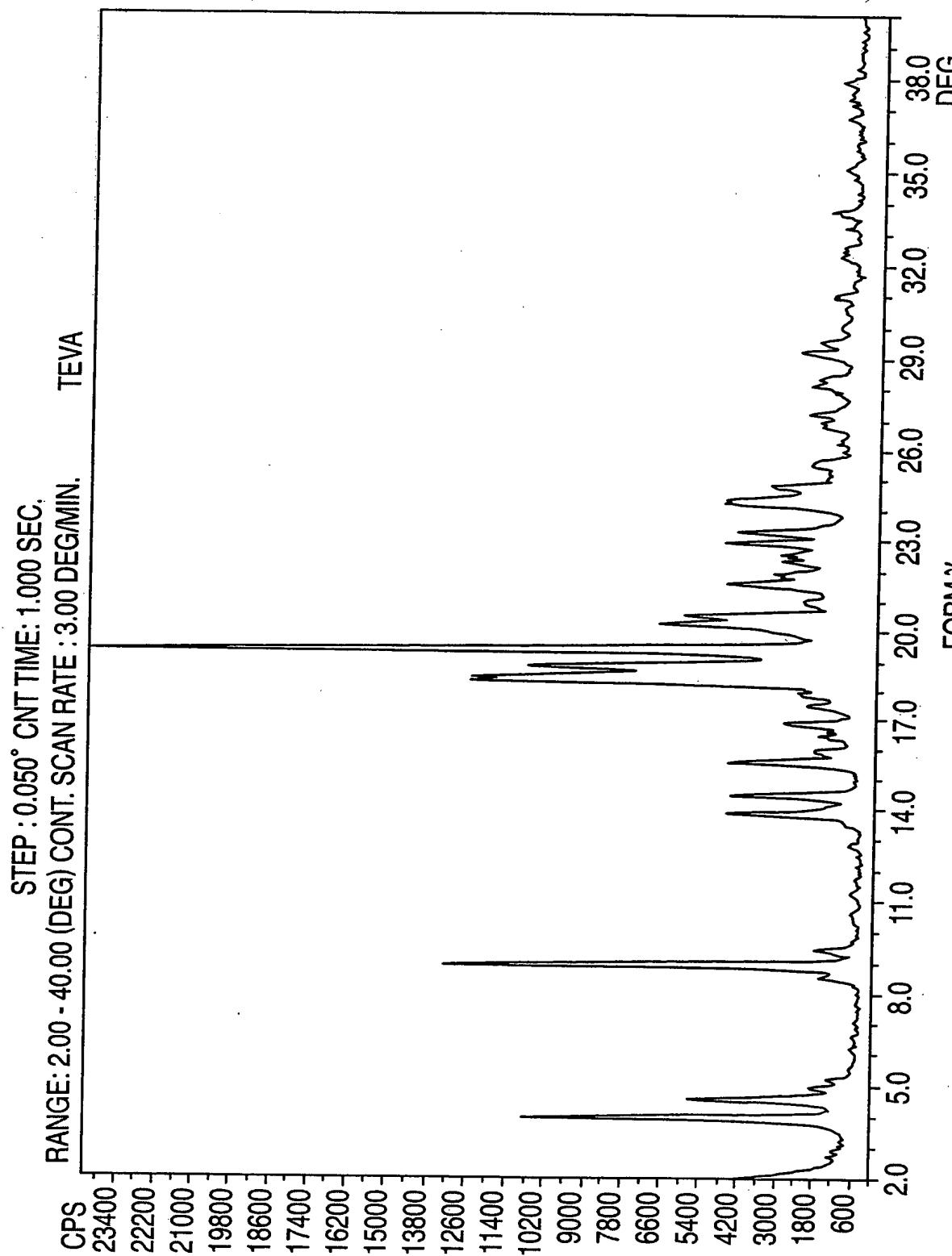


FIG. 22  
FORM  $\beta$

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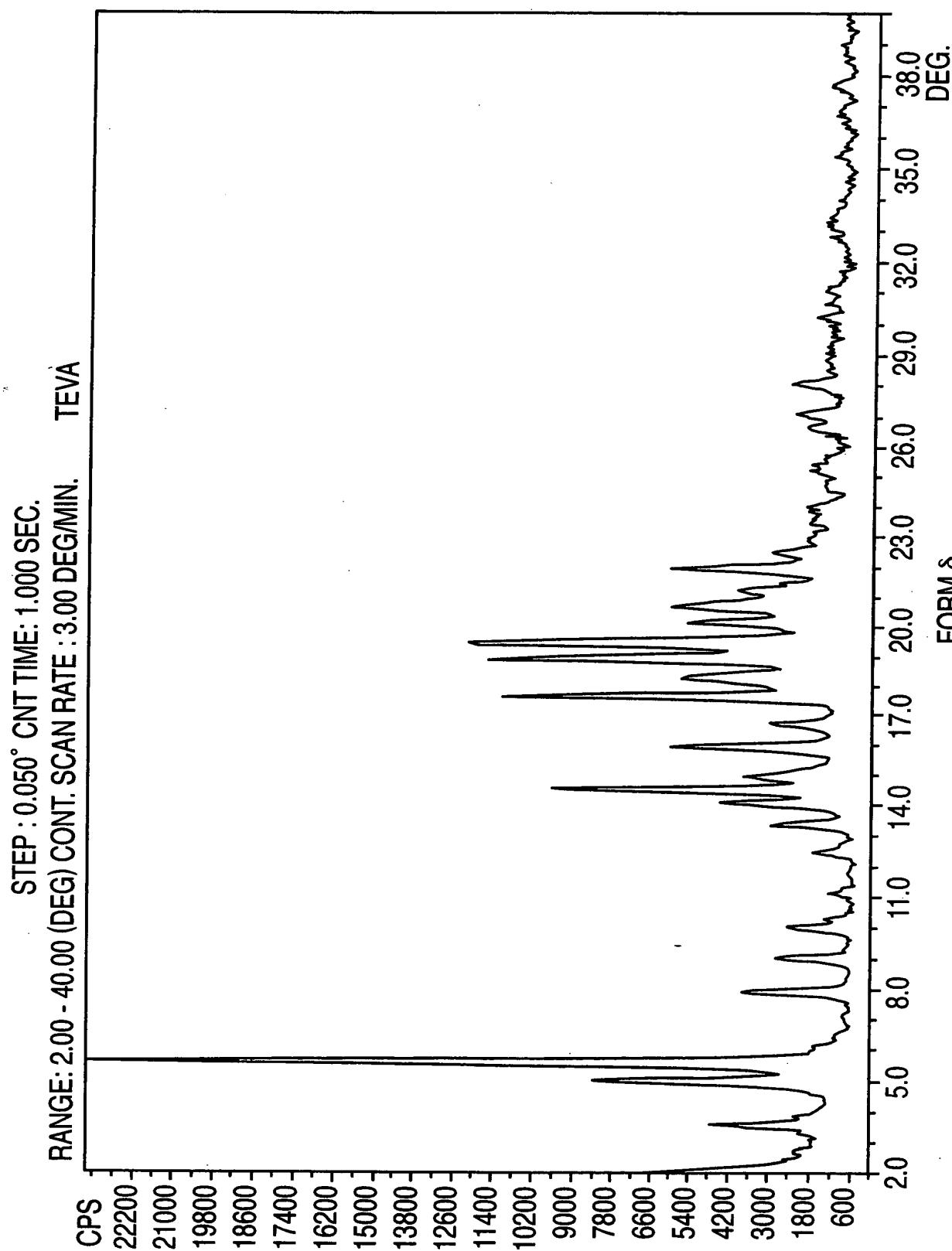
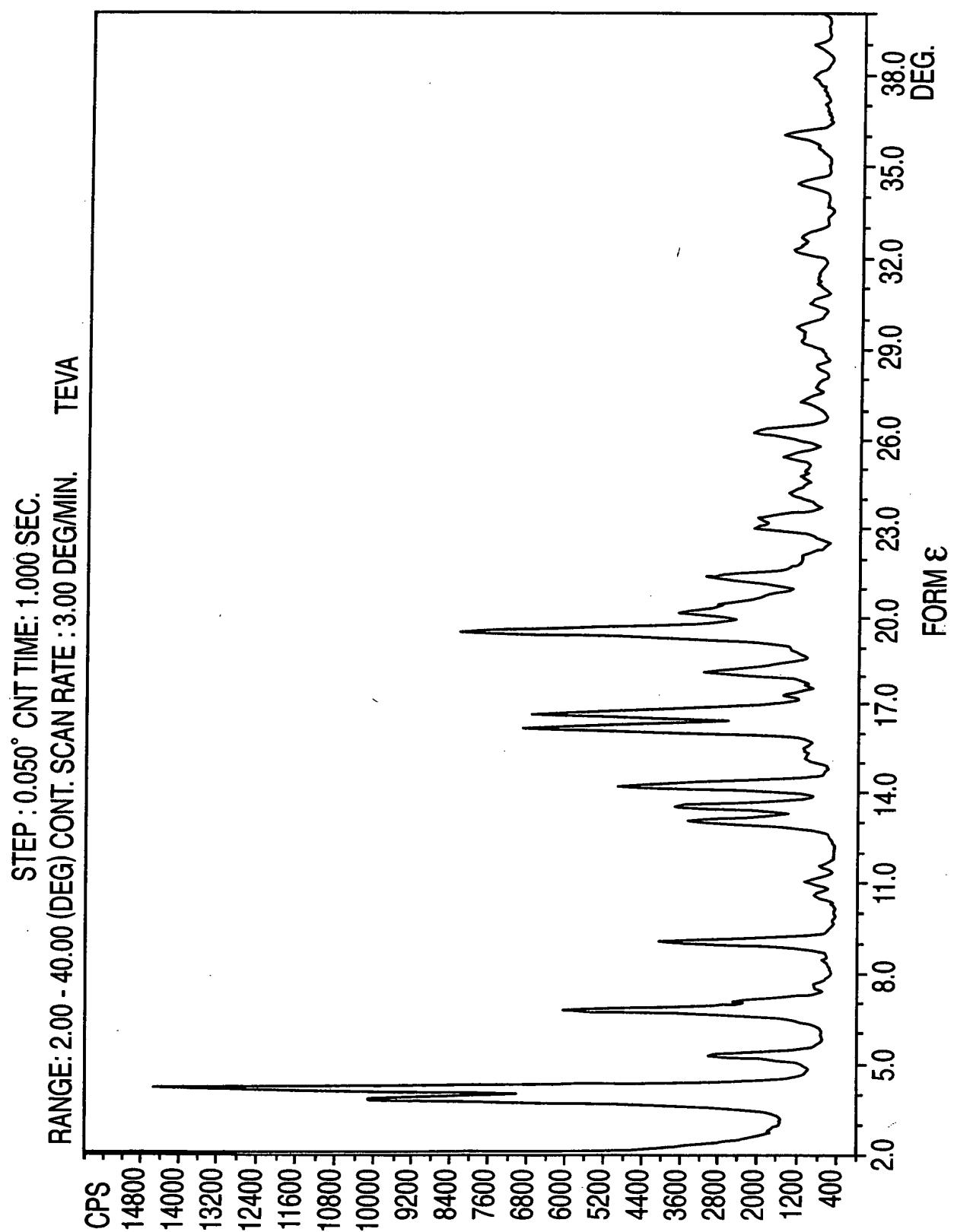


FIG. 24



SIGMA STEP : 0.050° CNT TIME: 1.000 SEC.  
RANGE: 2.00 - 40.00 (DEG) CONT. SCAN RATE : 3.00 DEG/MIN.

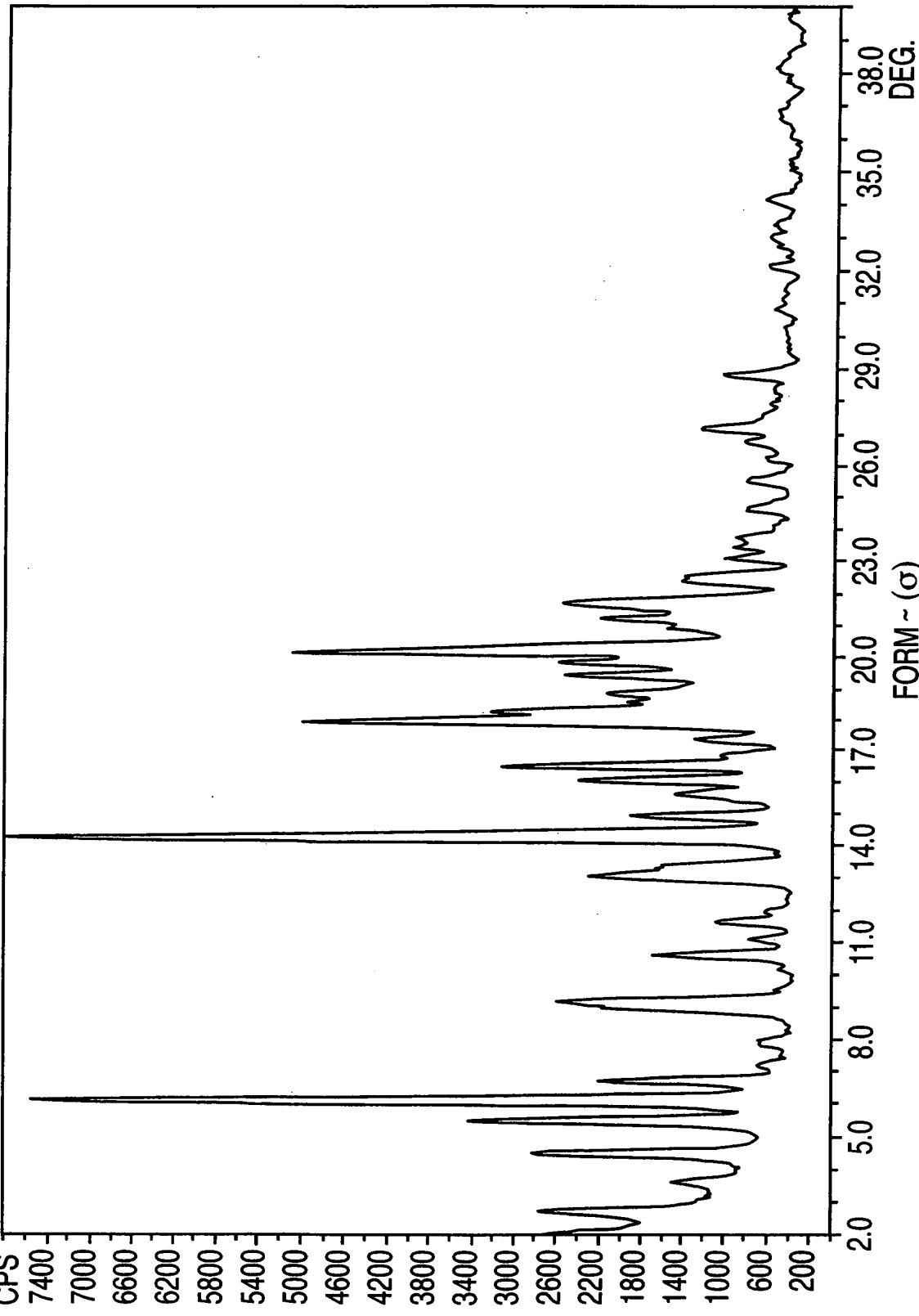
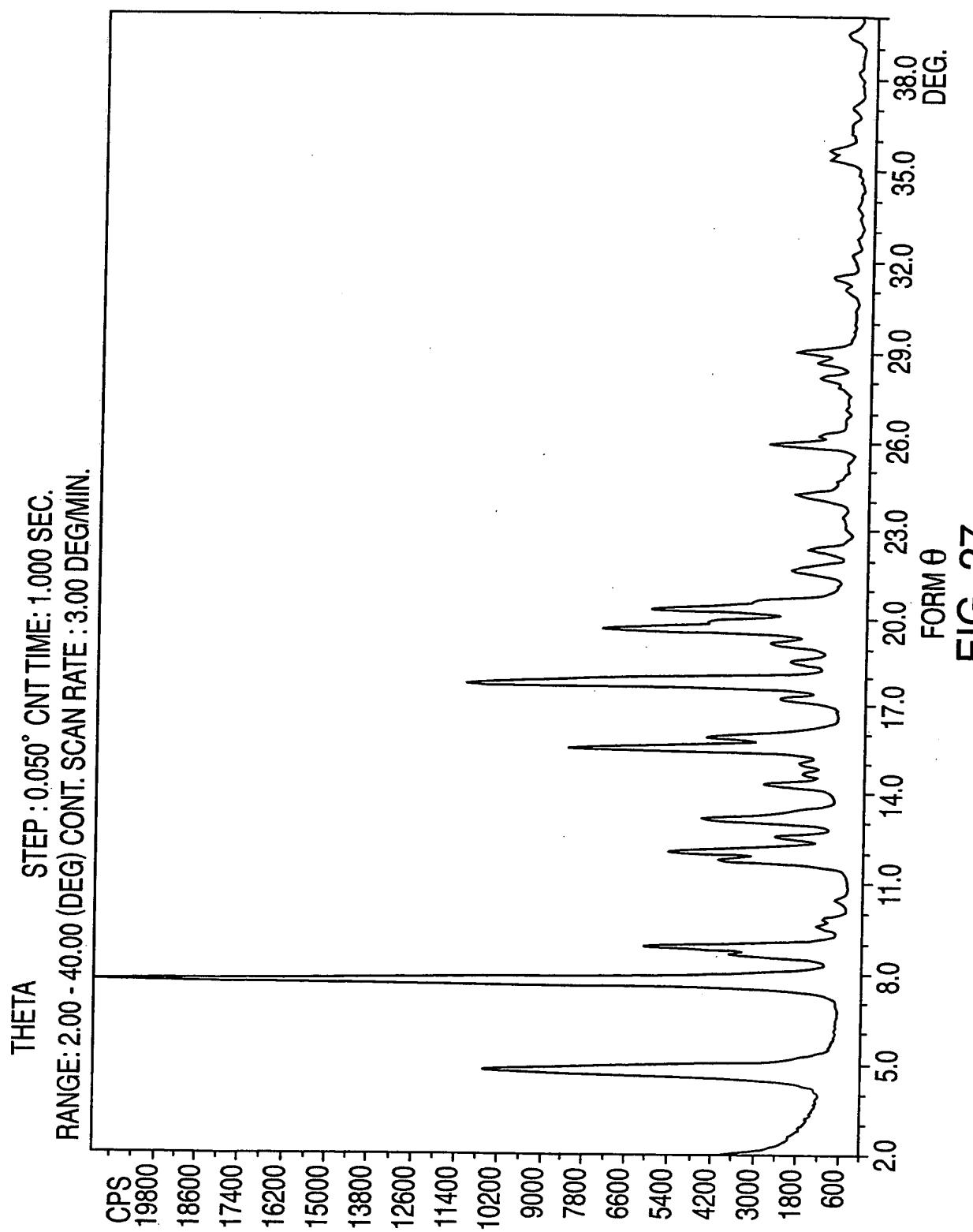
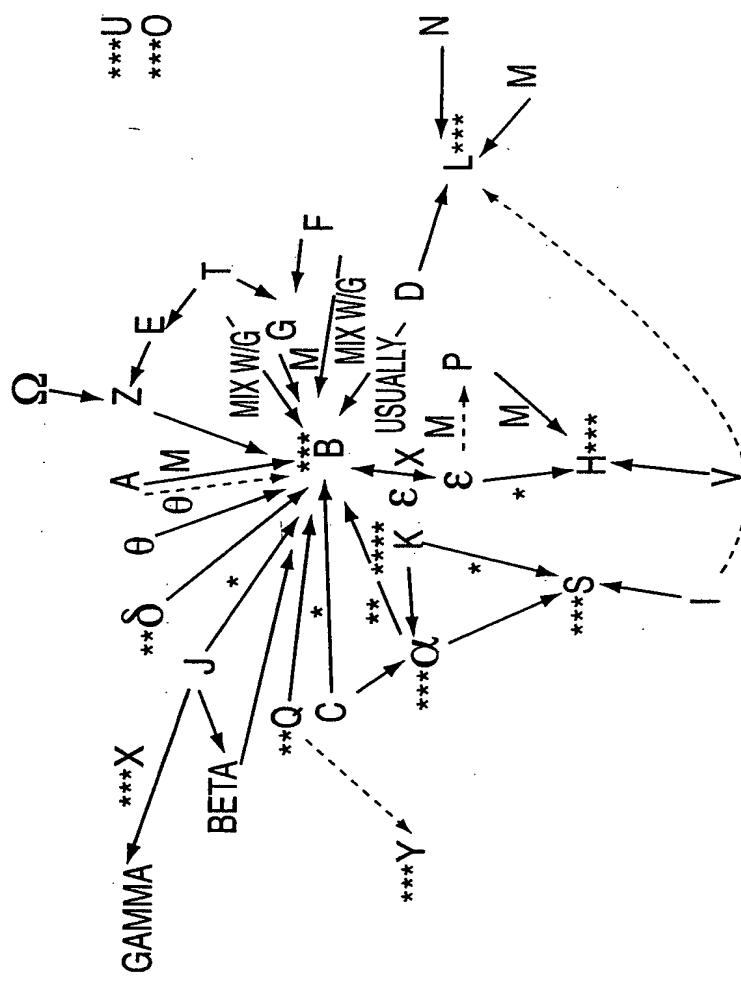


FIG. 26

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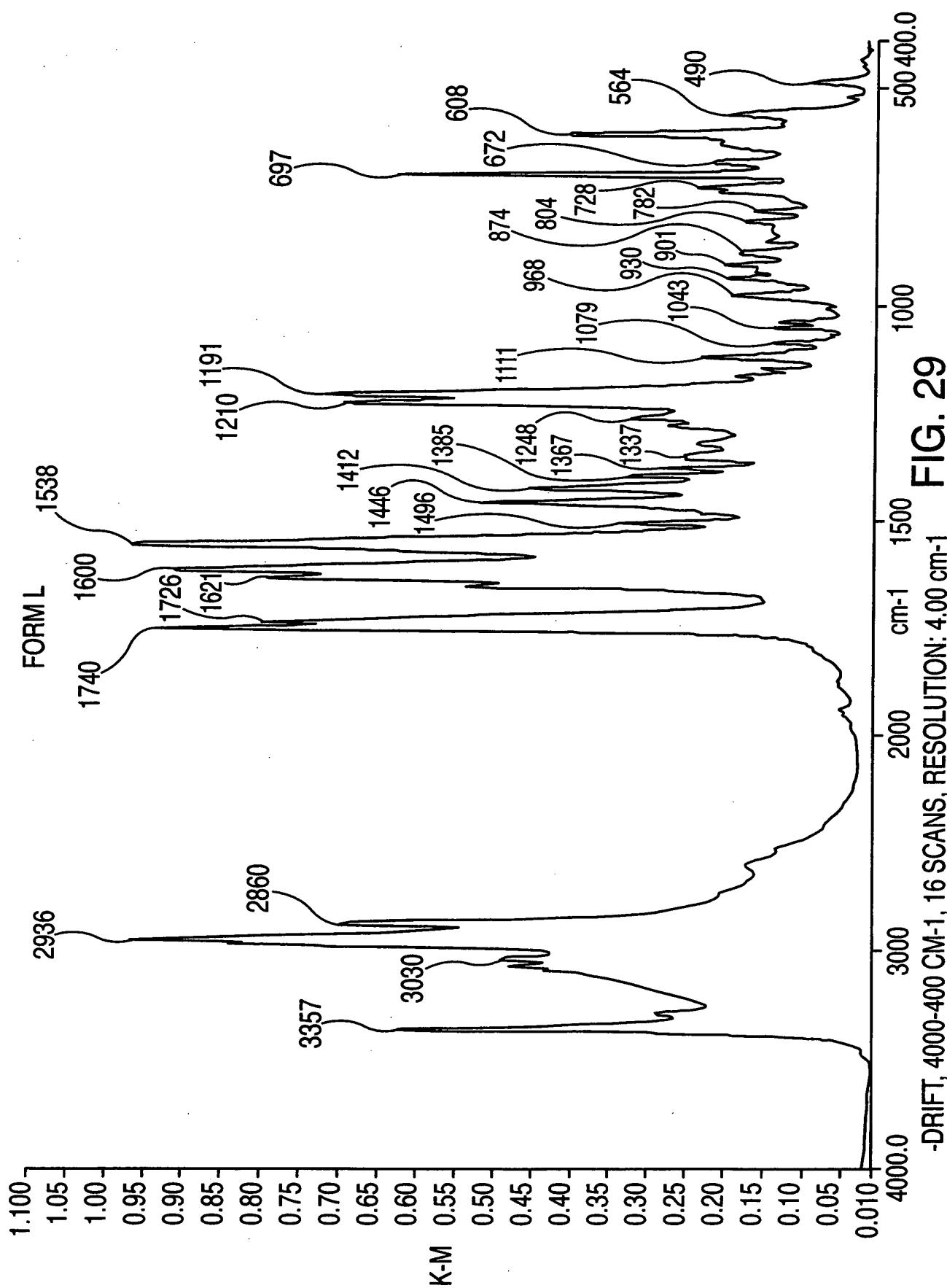


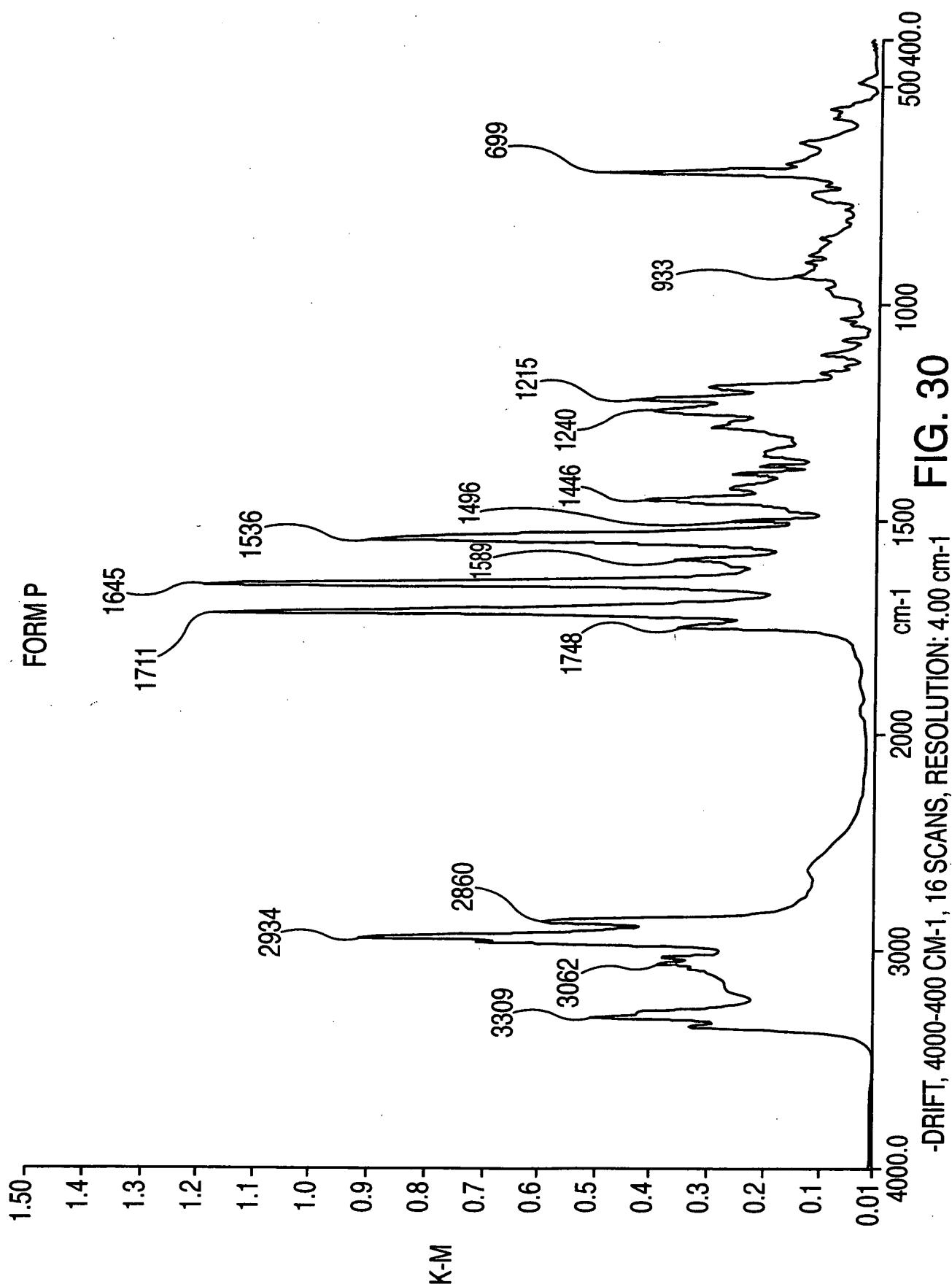


- \* TRANSFORMATION MAY PROCEED THROUGH ANOTHER TERM.
- \*\* THERMALLY STABLE AT LOWER HEATING TEMPERATURES (~50 °C).
- \*\*\* THERMALLY STABLE FORMS.
- TRANSFORMATION AFTER STORAGE AT ROOM TEMPERATURE.
- m MIXTURE WITH STARTING FORM.
- \*\*\*\* WHEN STARTING MATERIAL CONTAINS SEEDS.
- soi RESULTS MIGHT VARY DEPENDING ON THE SOLVATE OF FORM EPSILON USED.

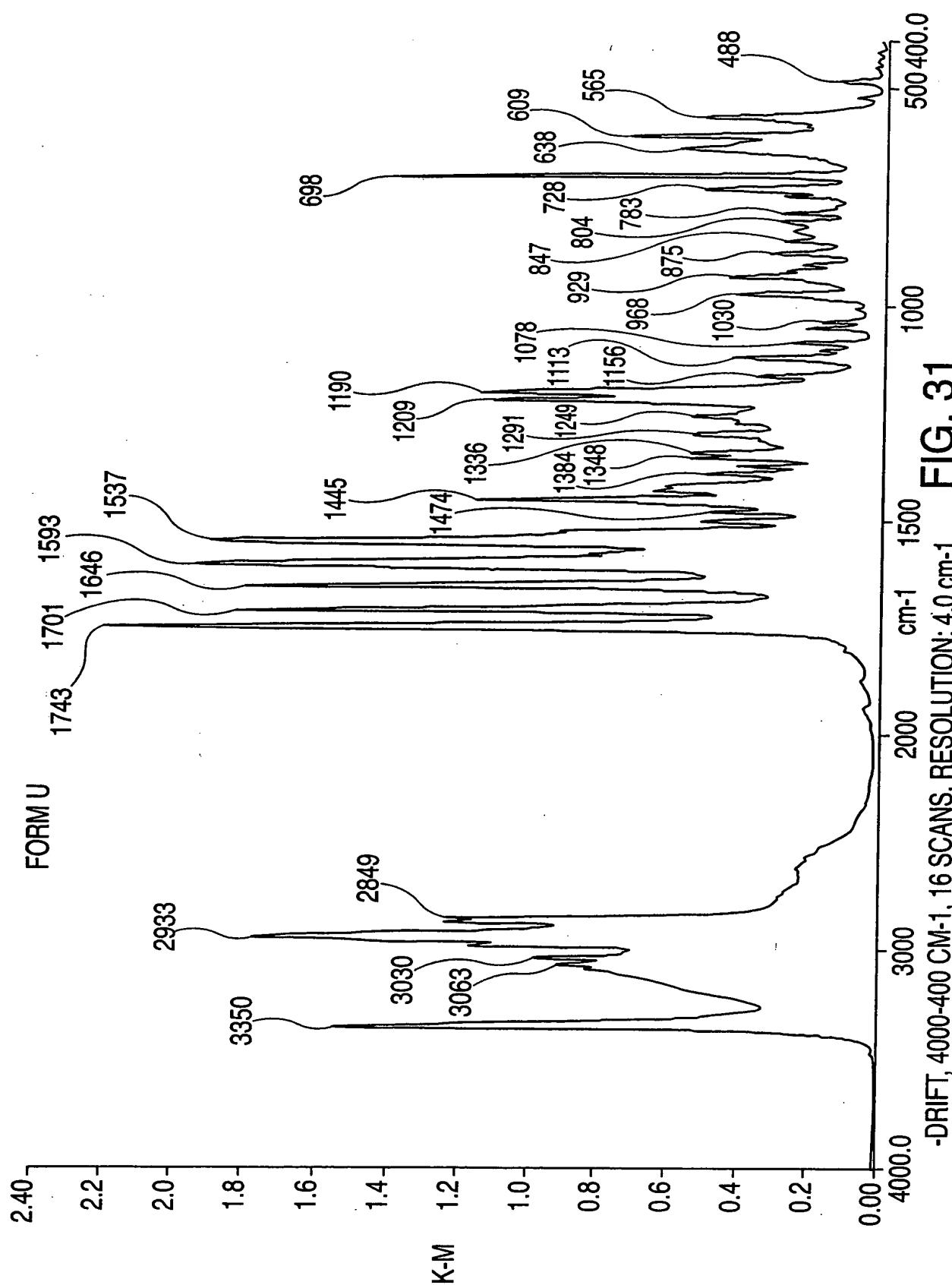
FIG. 28  
 THERMAL STABILITY CHART

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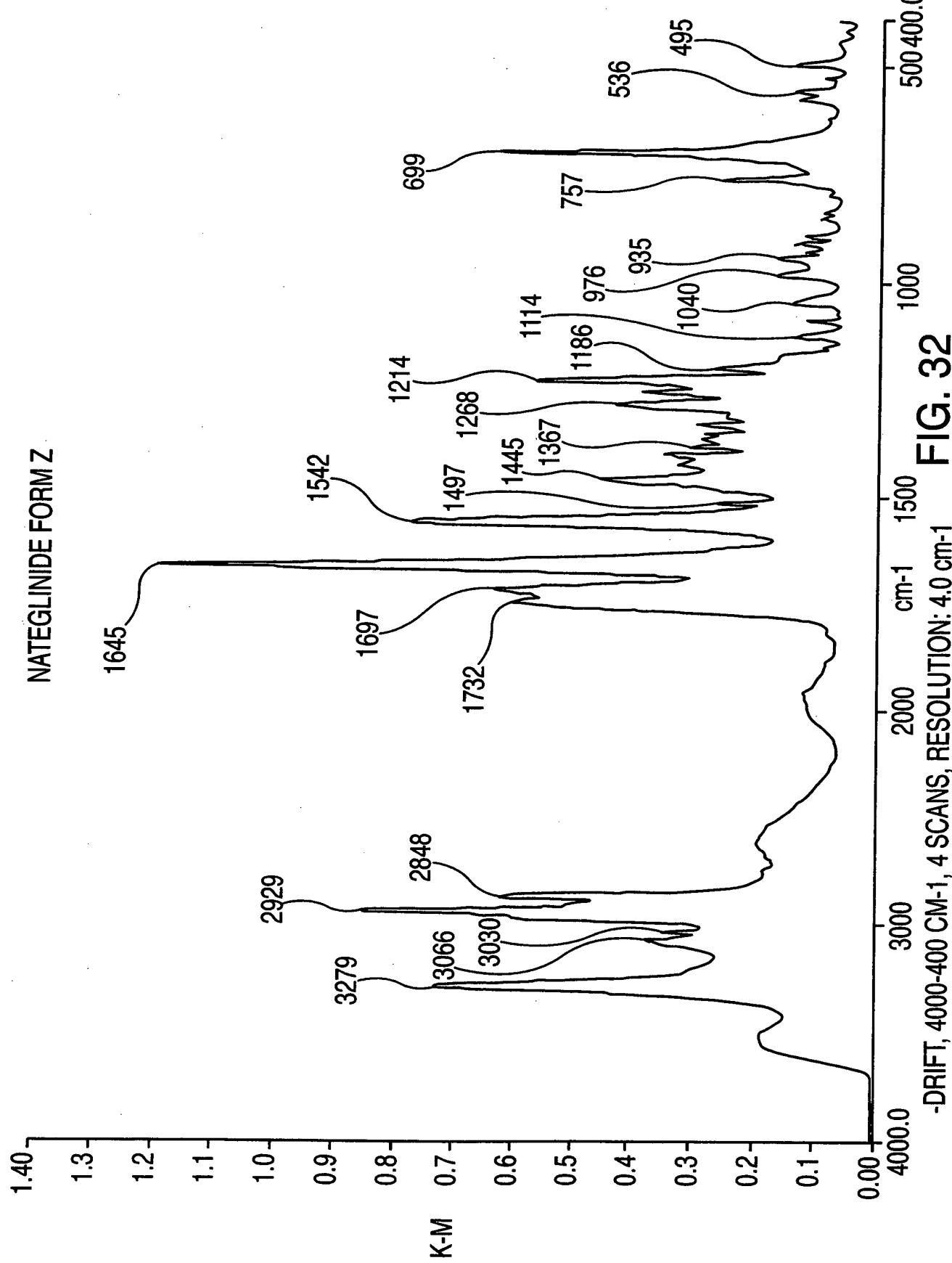


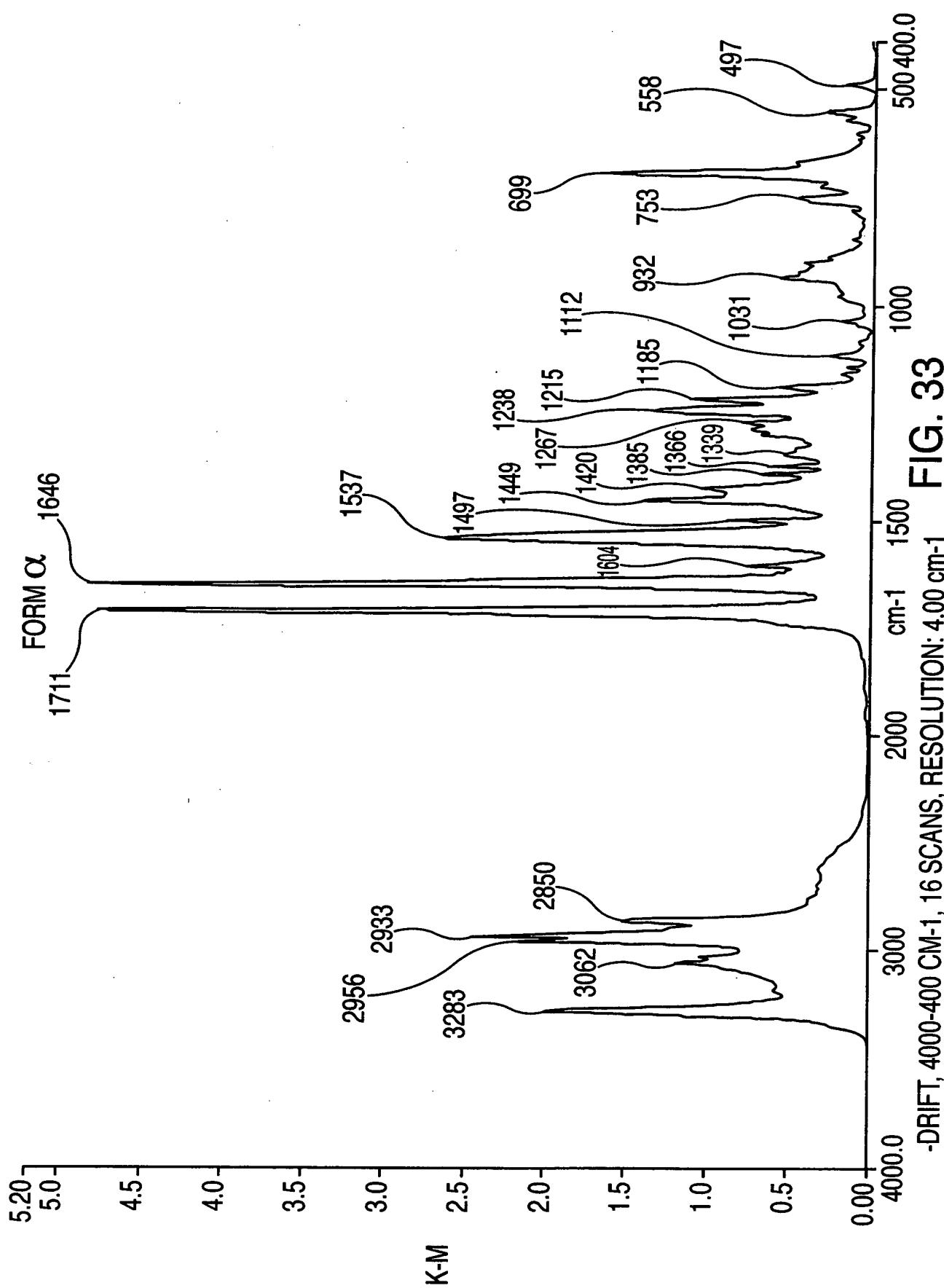


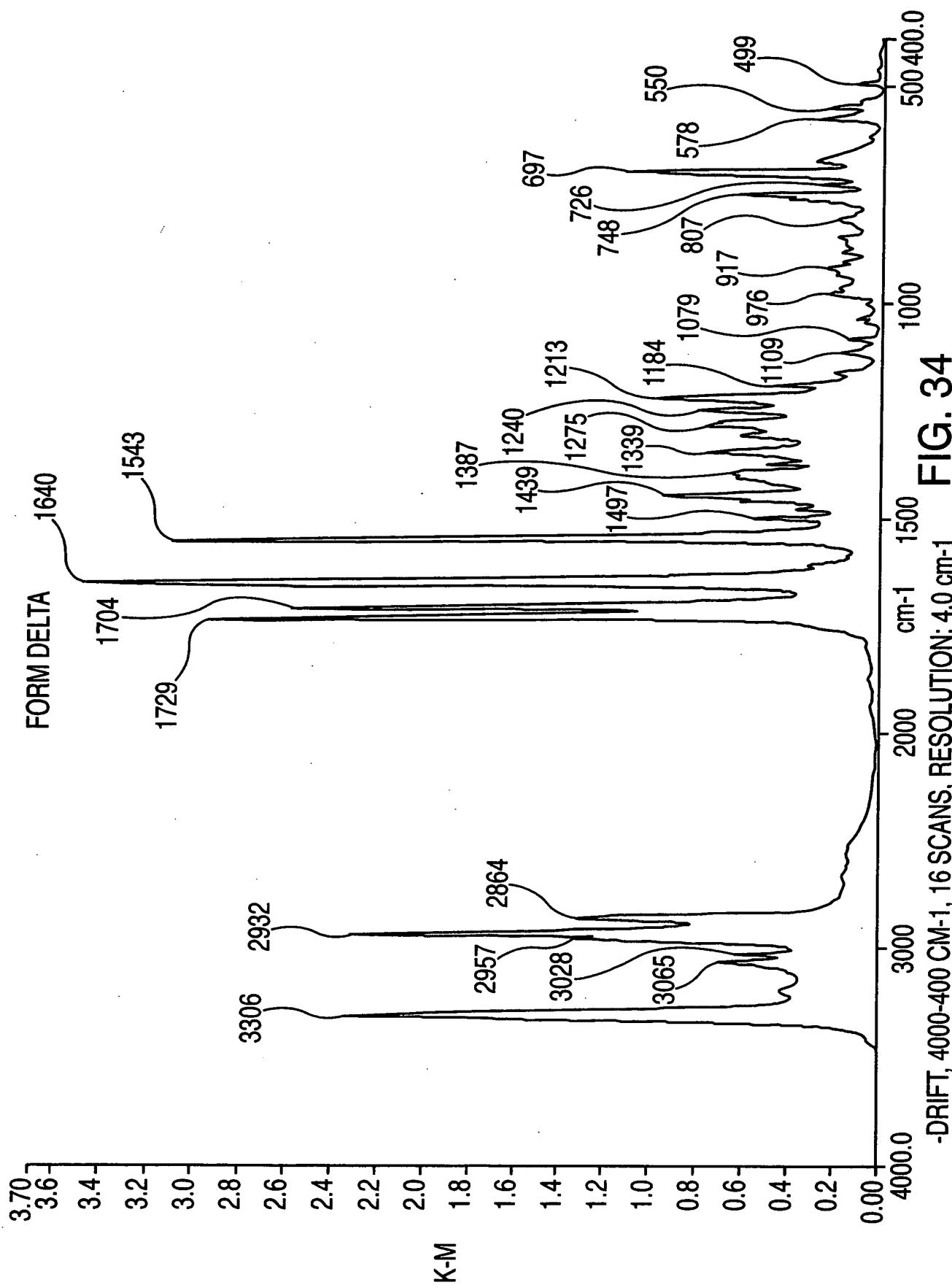
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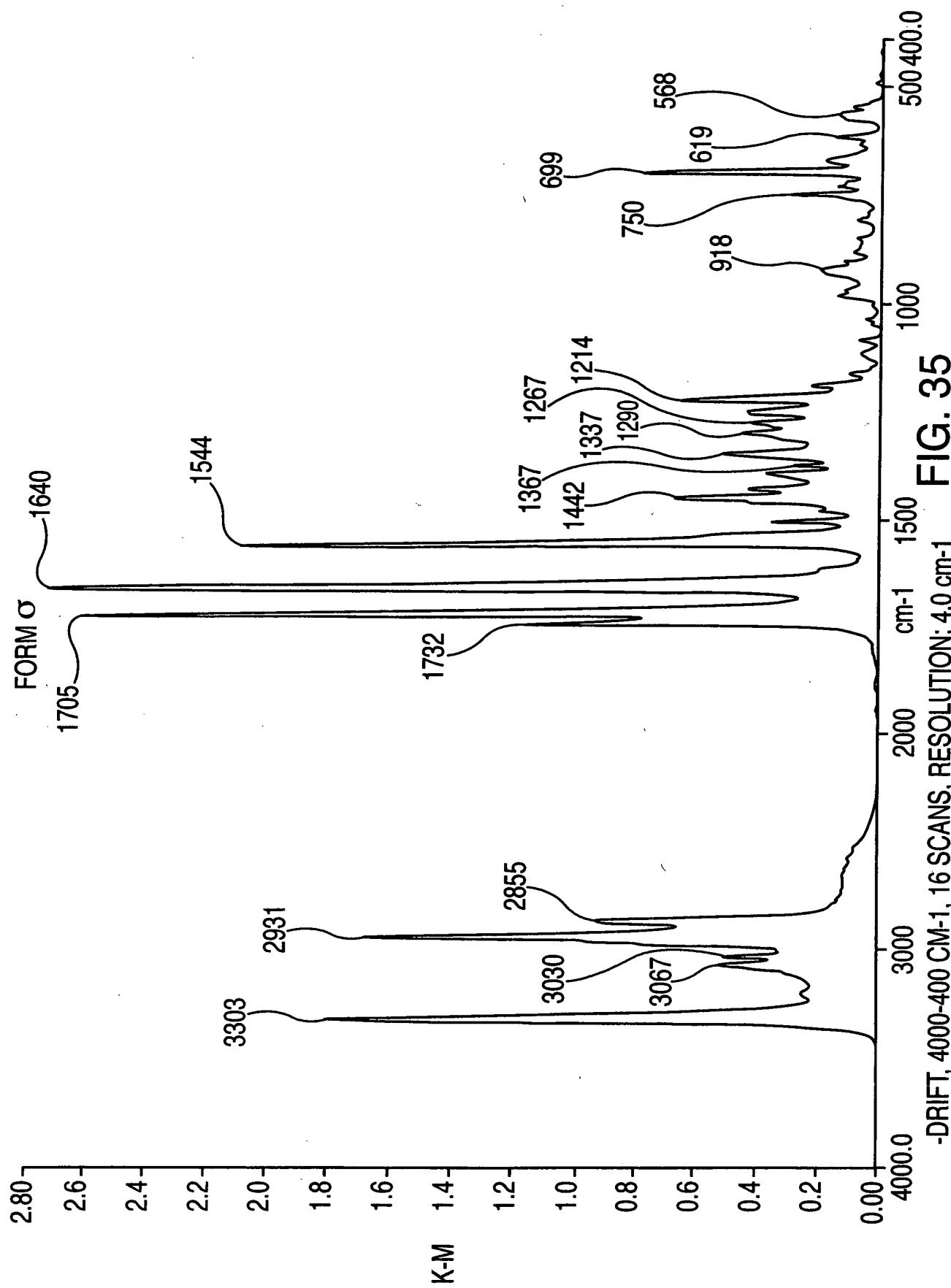
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-DRIFT, 4000-400 CM-1, 16 SCANS, RESOLUTION: 4.0 cm-1 FIG. 34



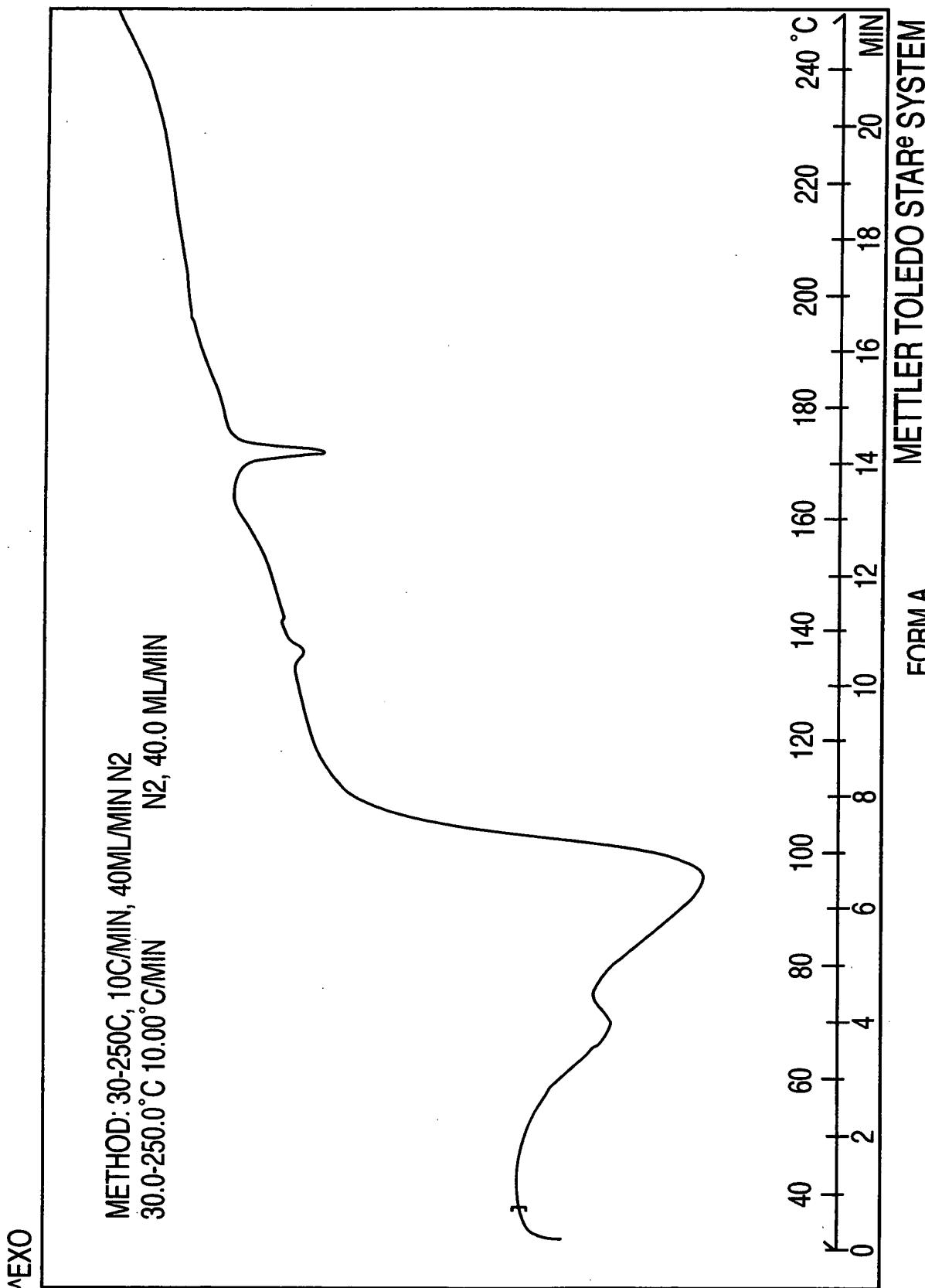
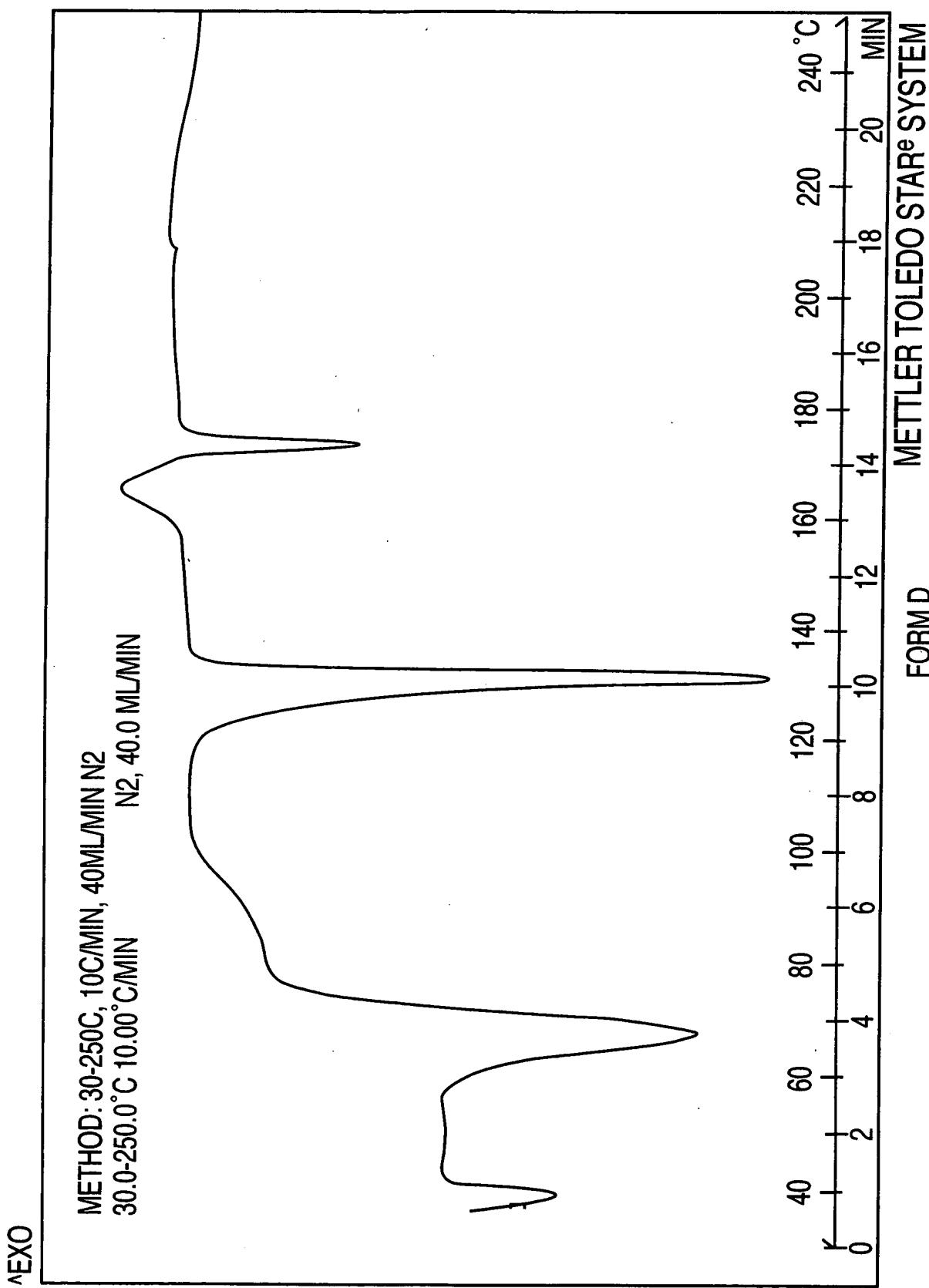
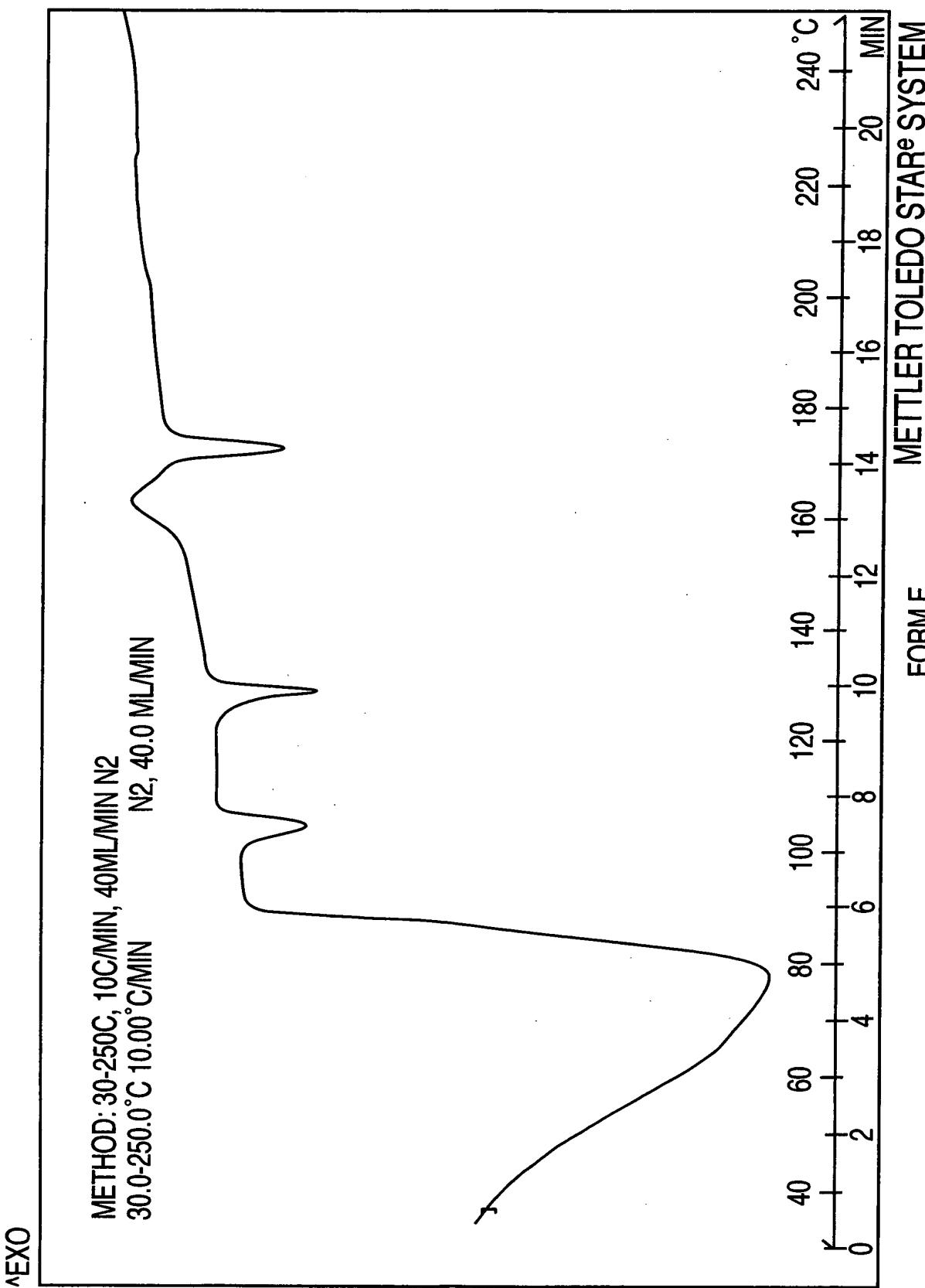


FIG. 36





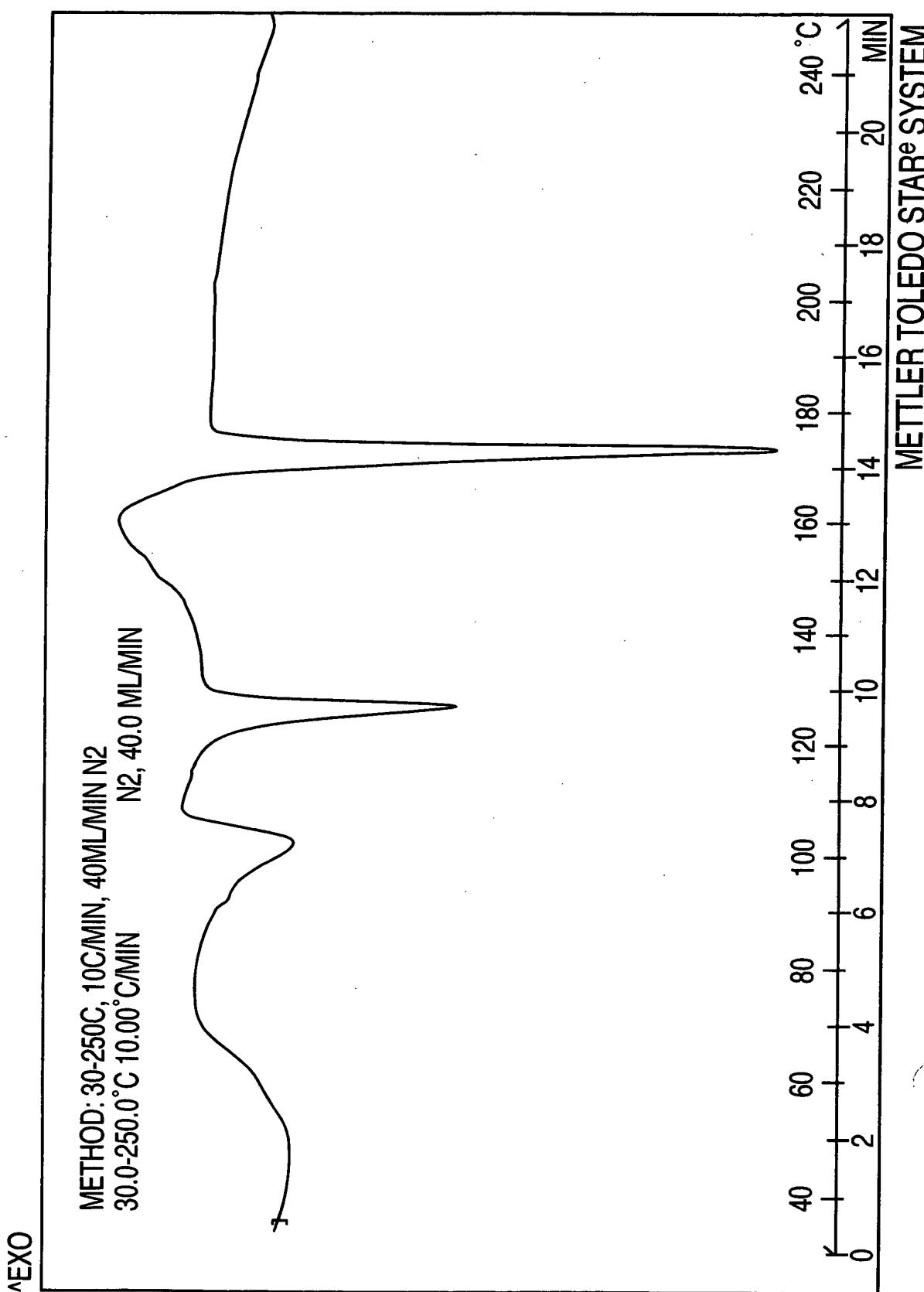


FIG. 39

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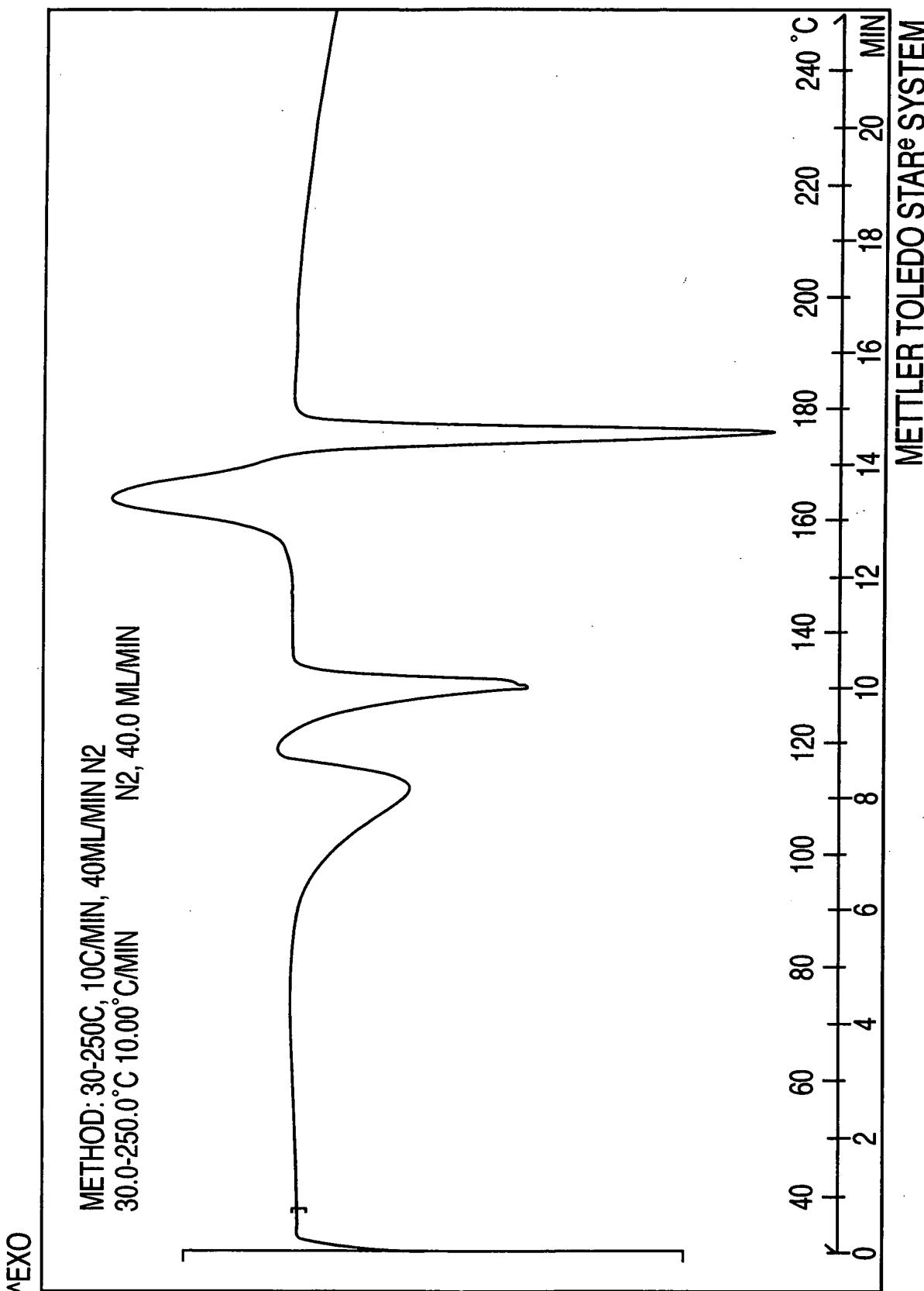
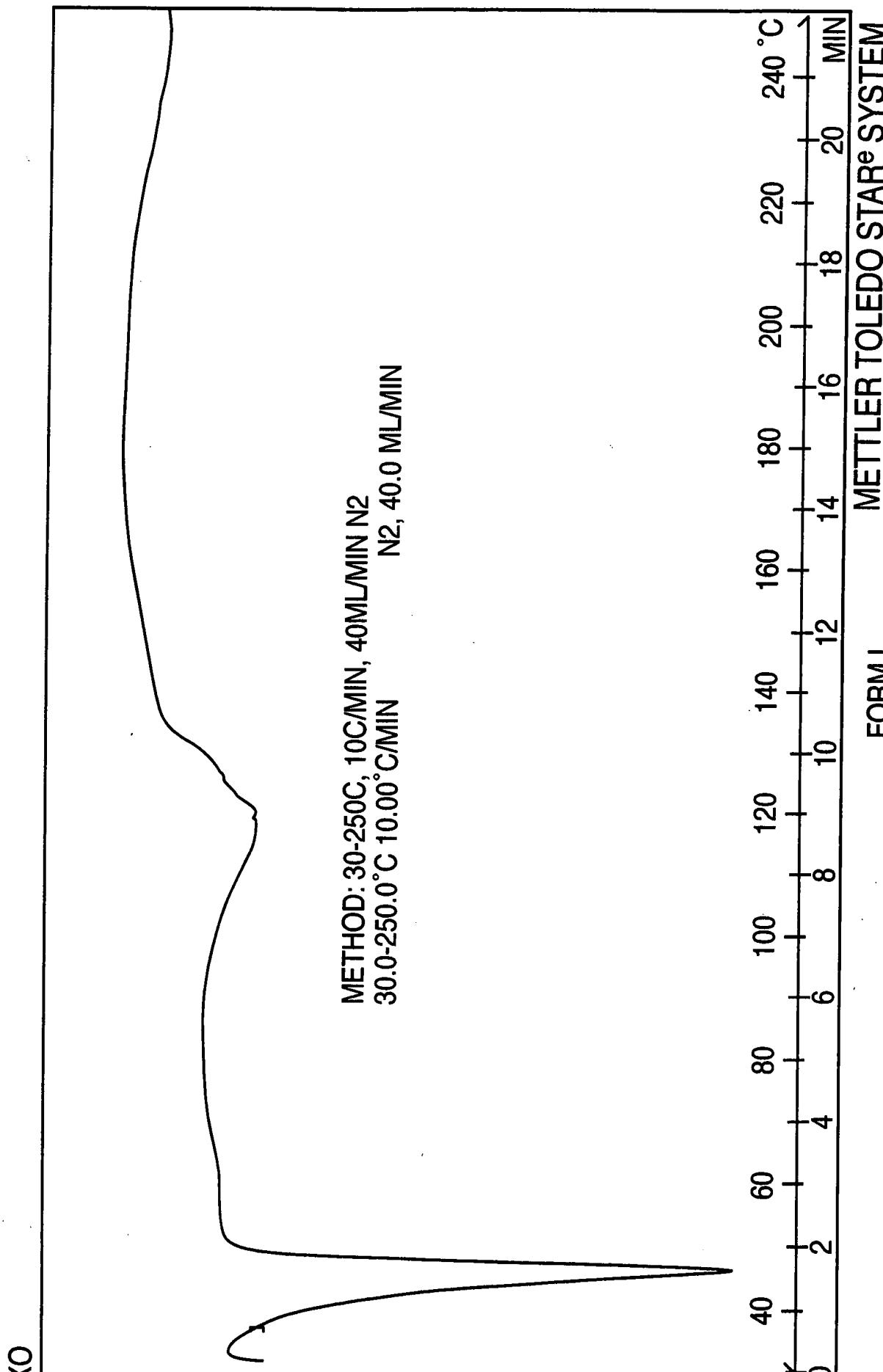
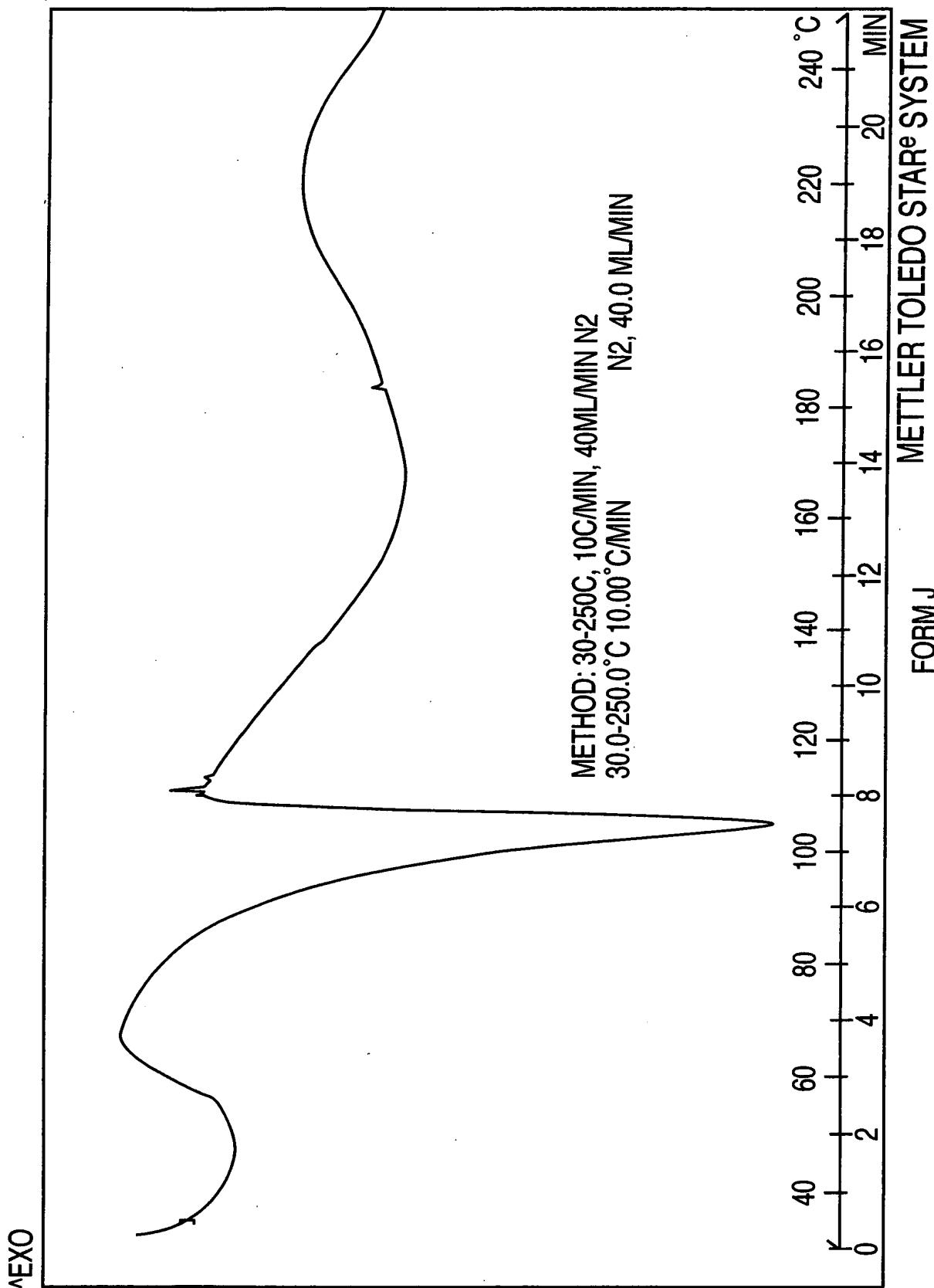
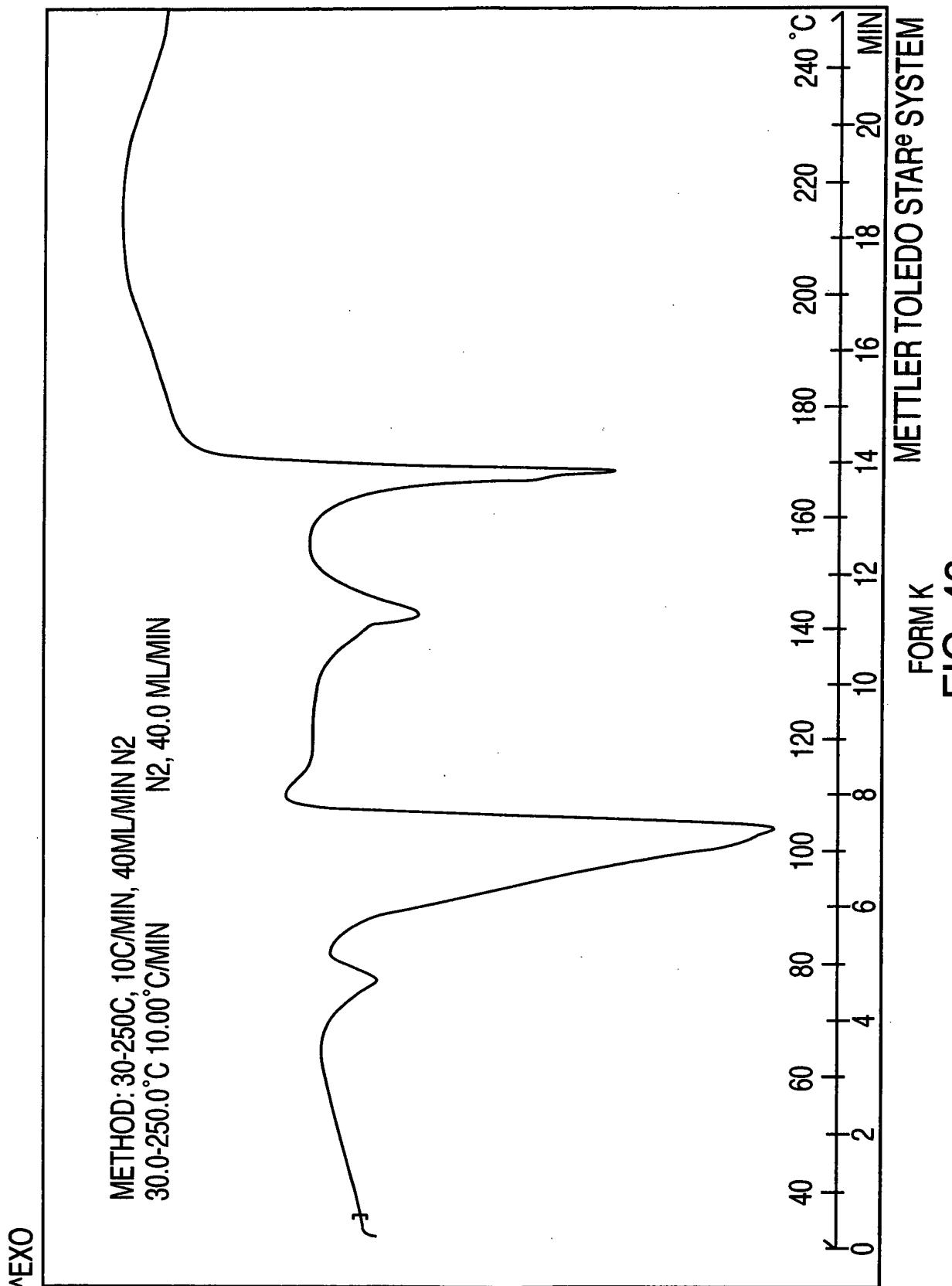
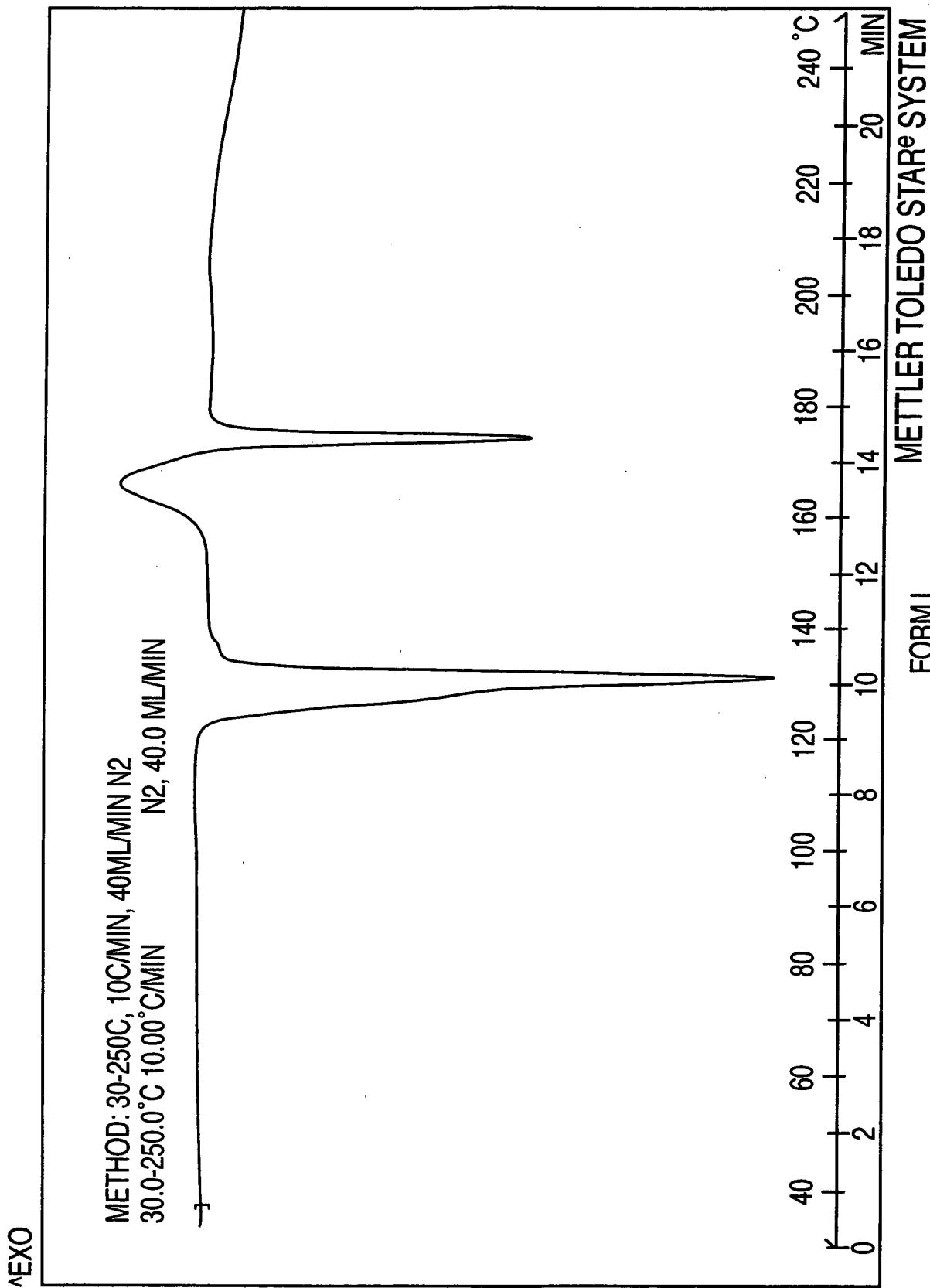


FIG. 40

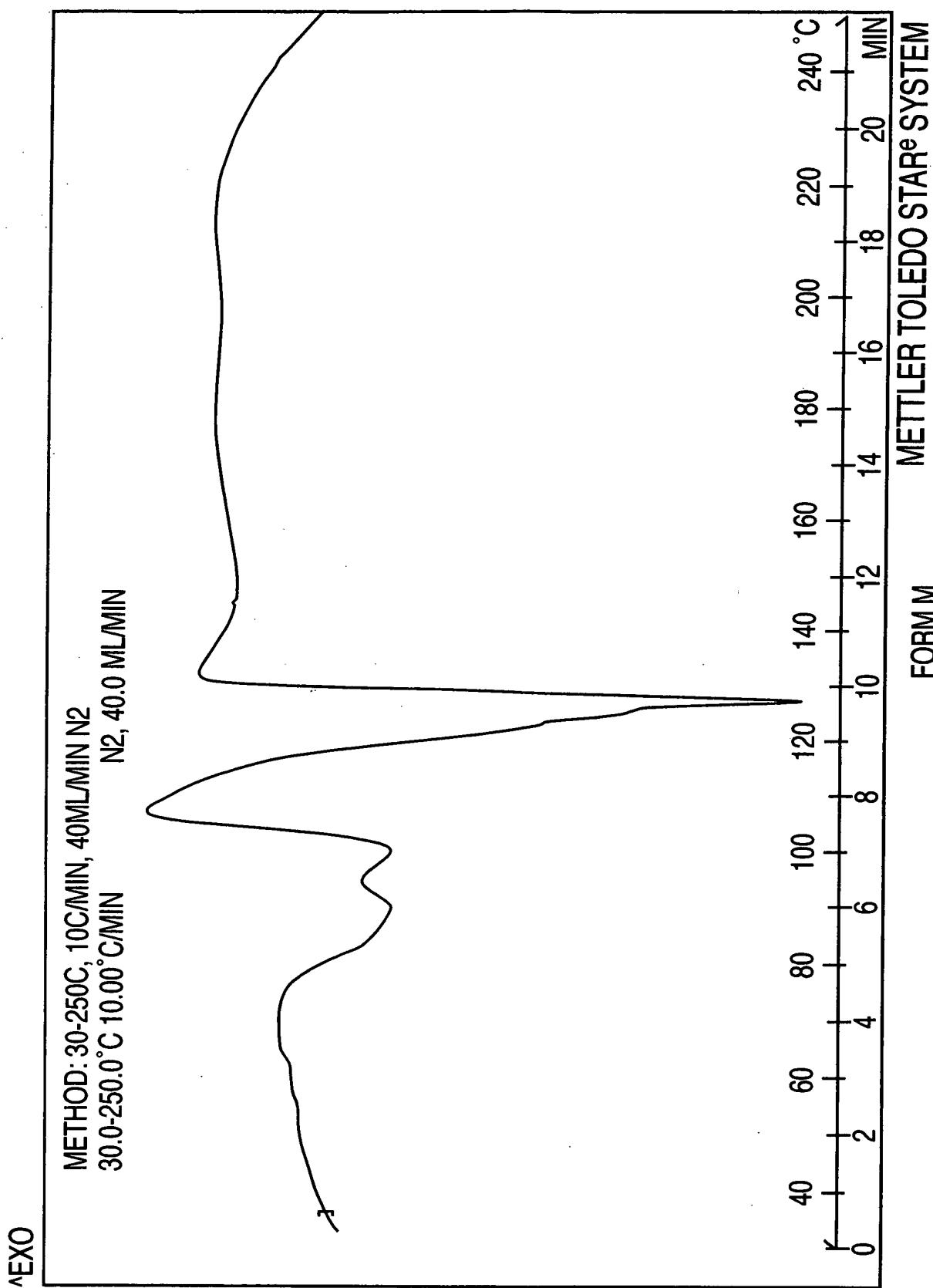


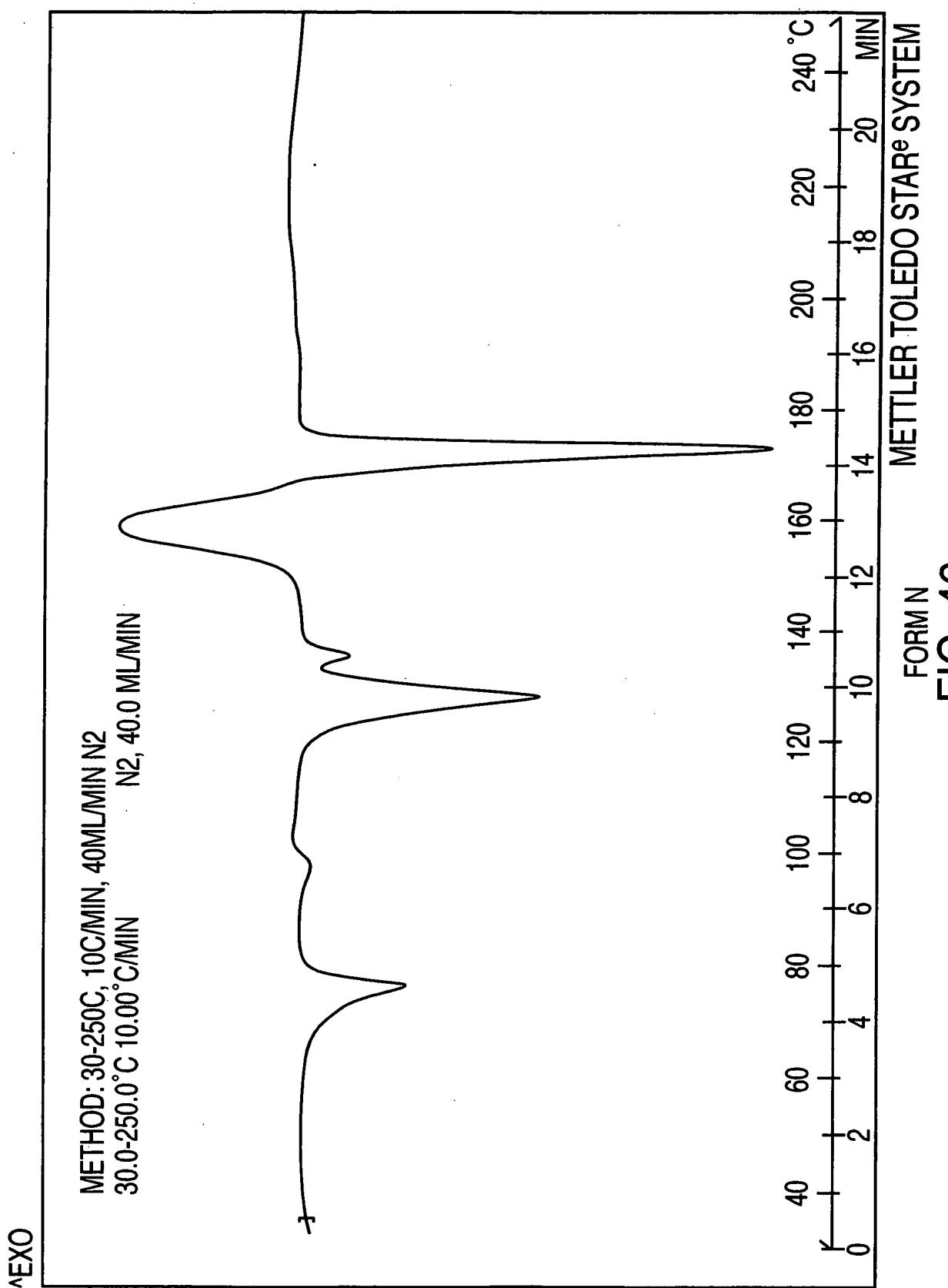


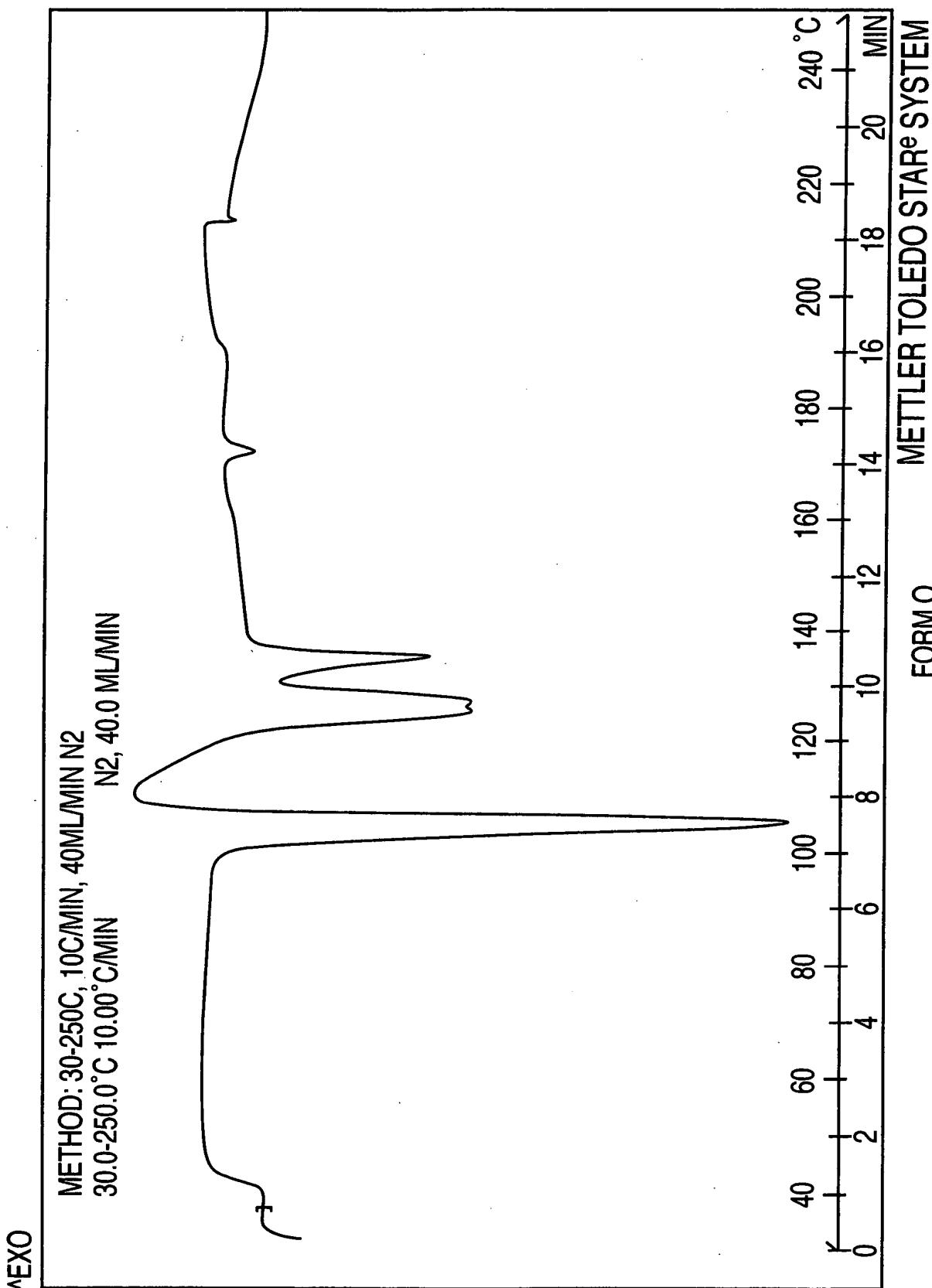




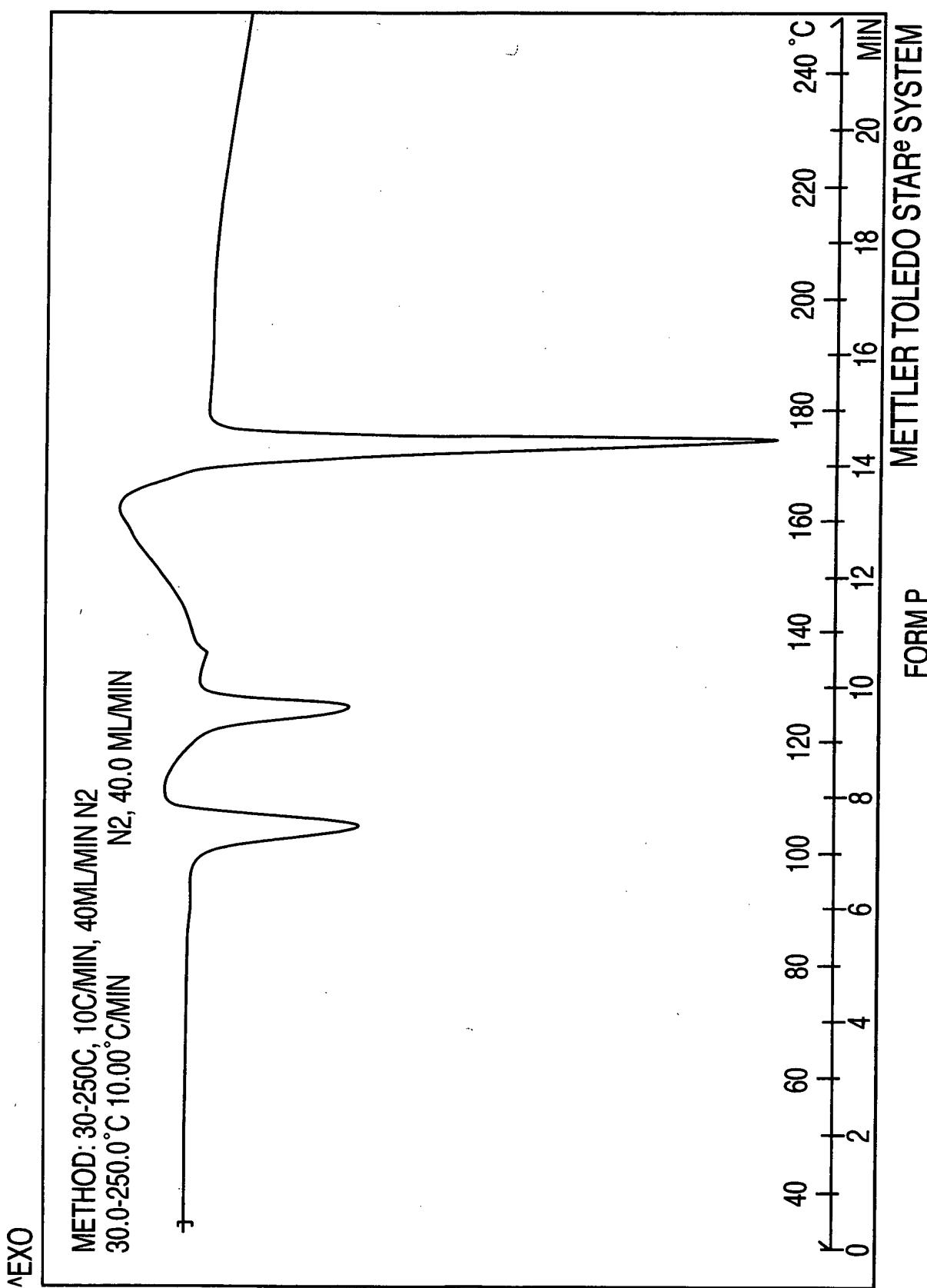
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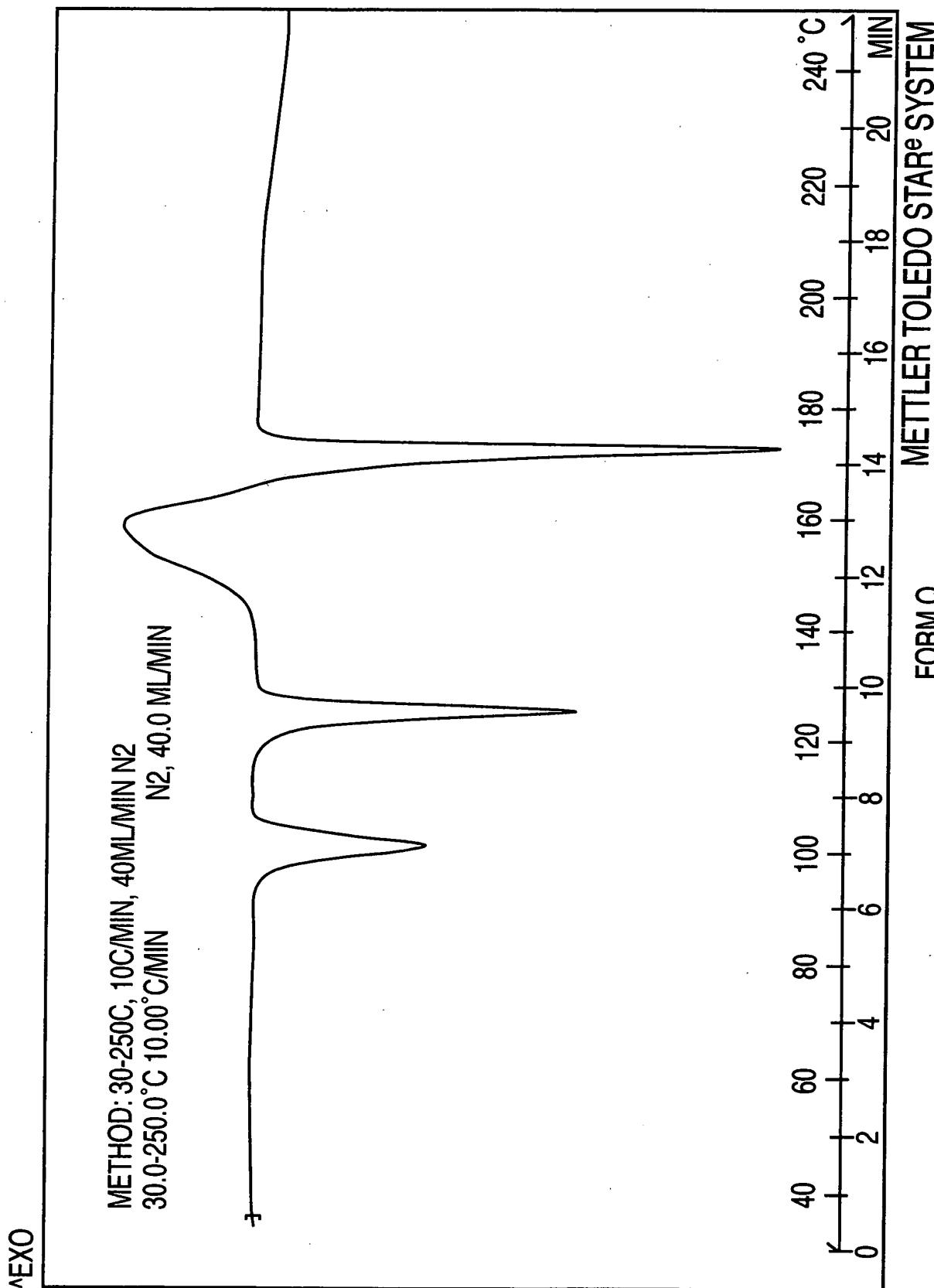




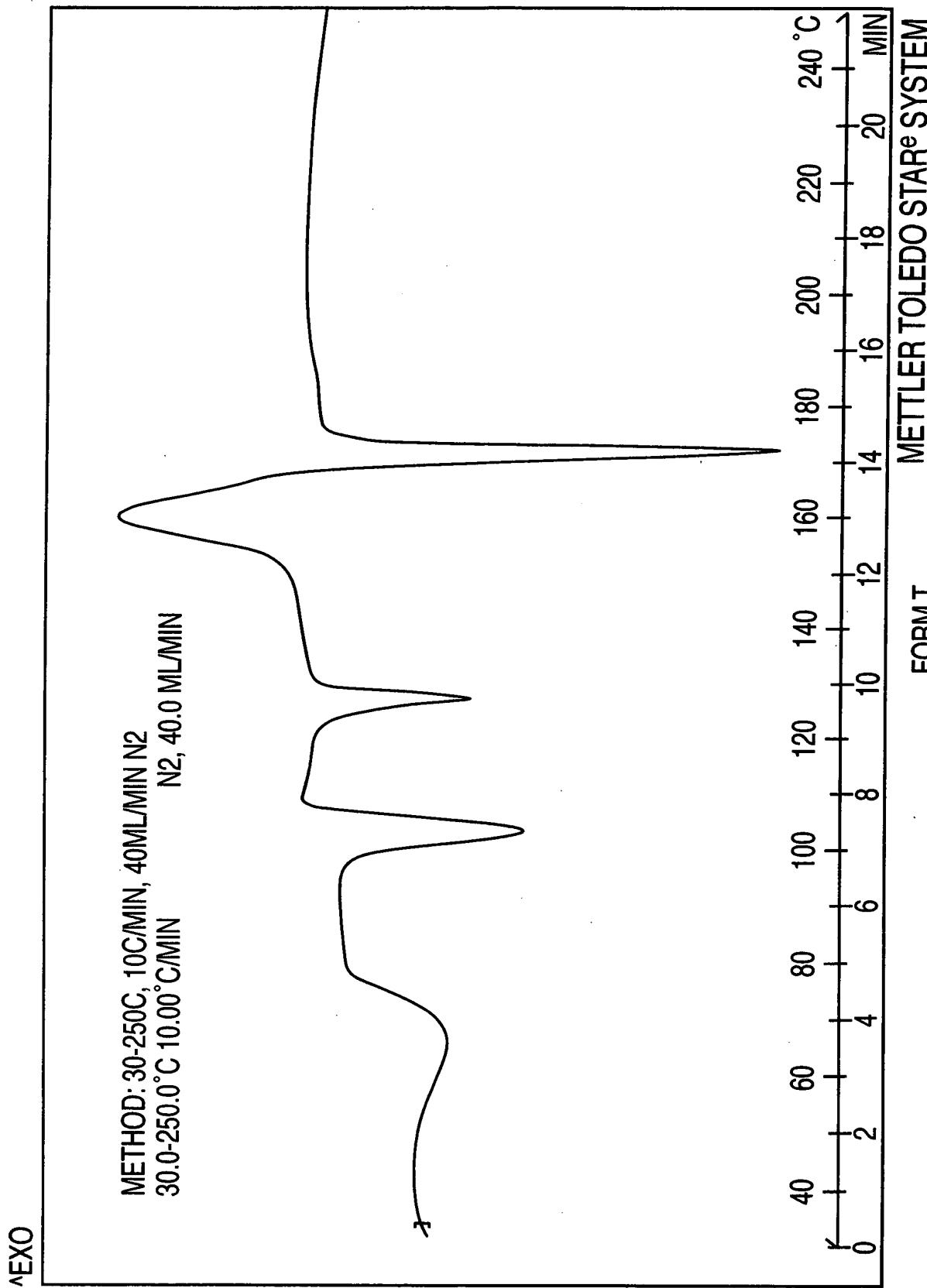


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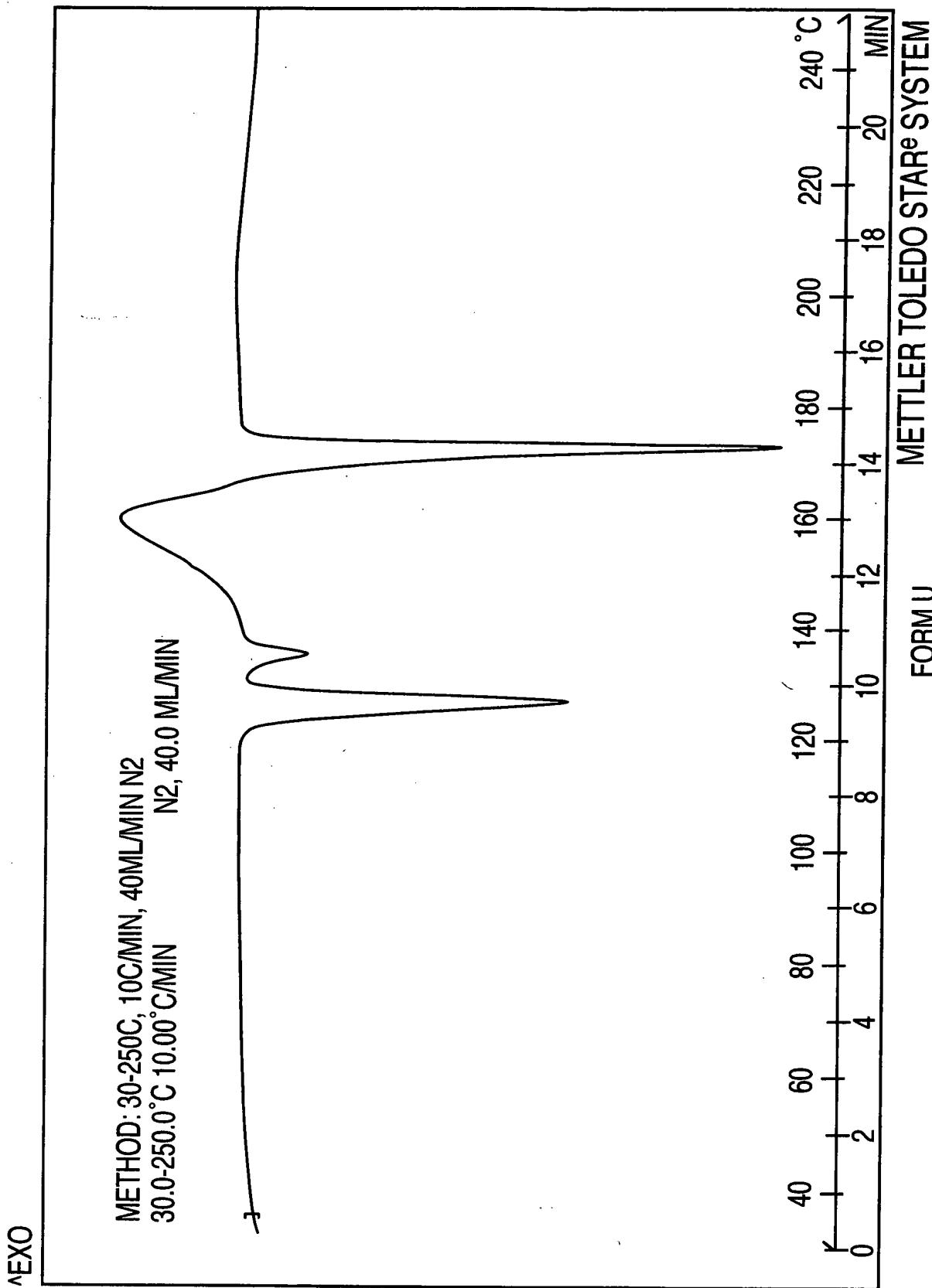
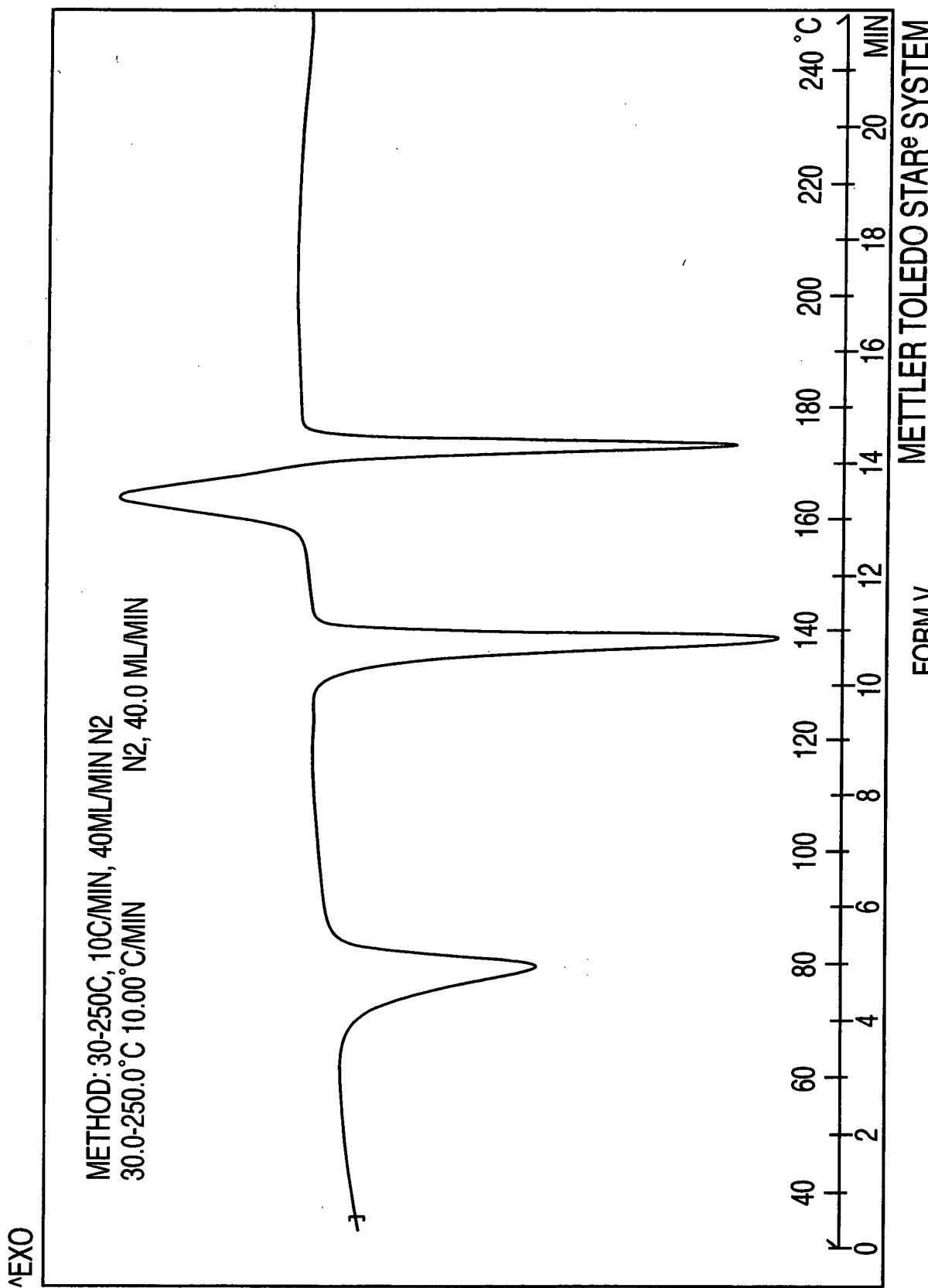
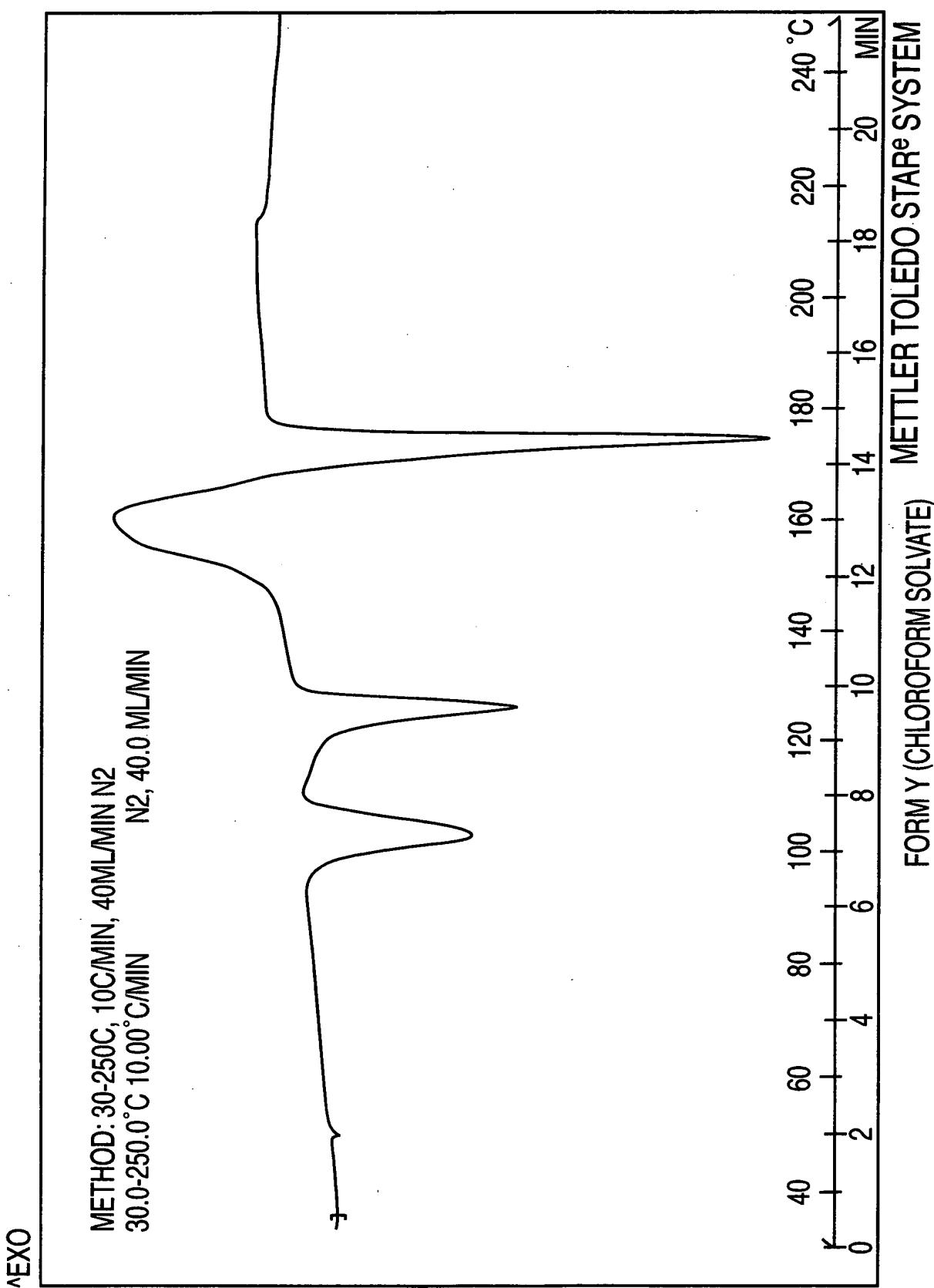
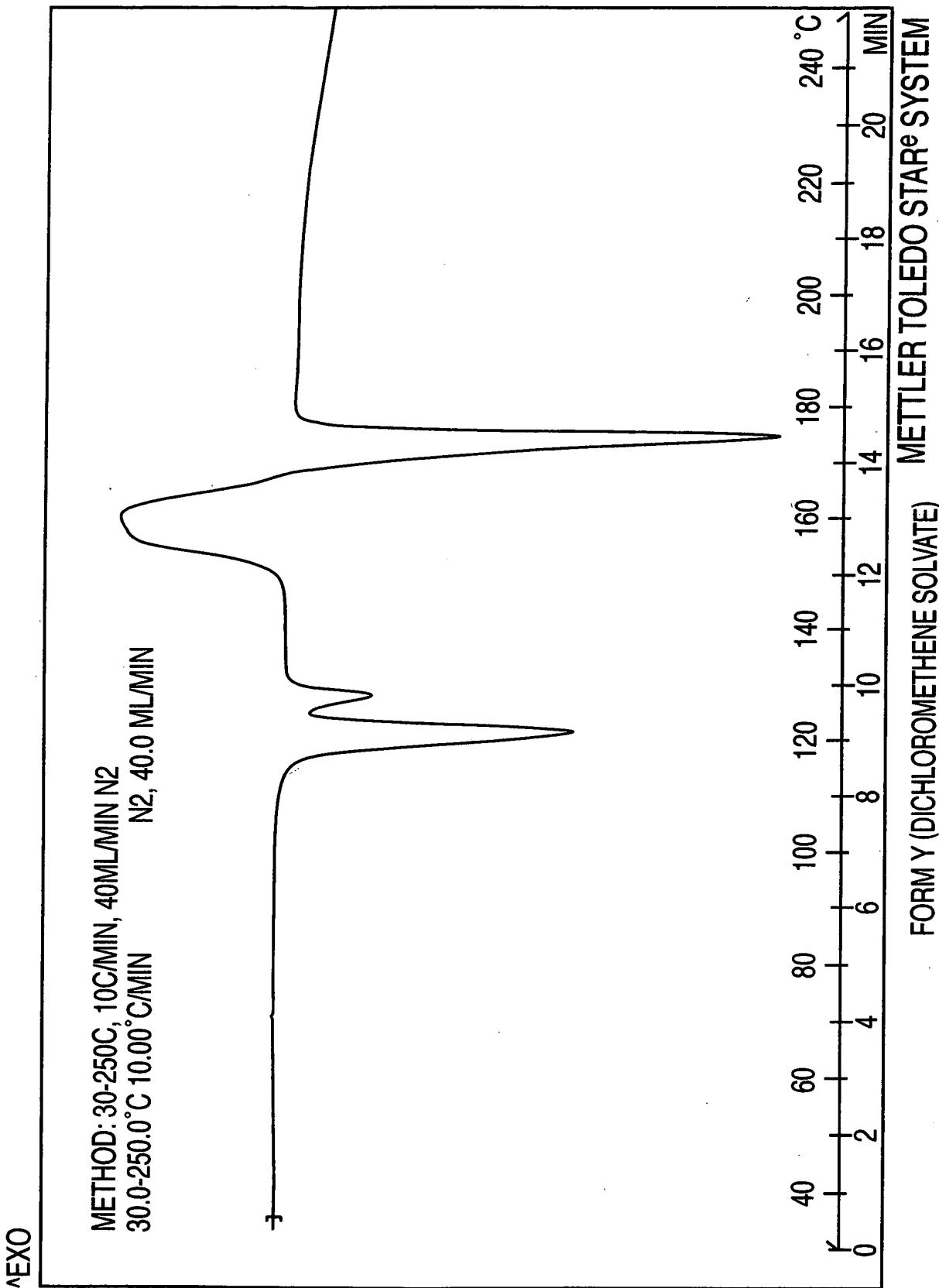


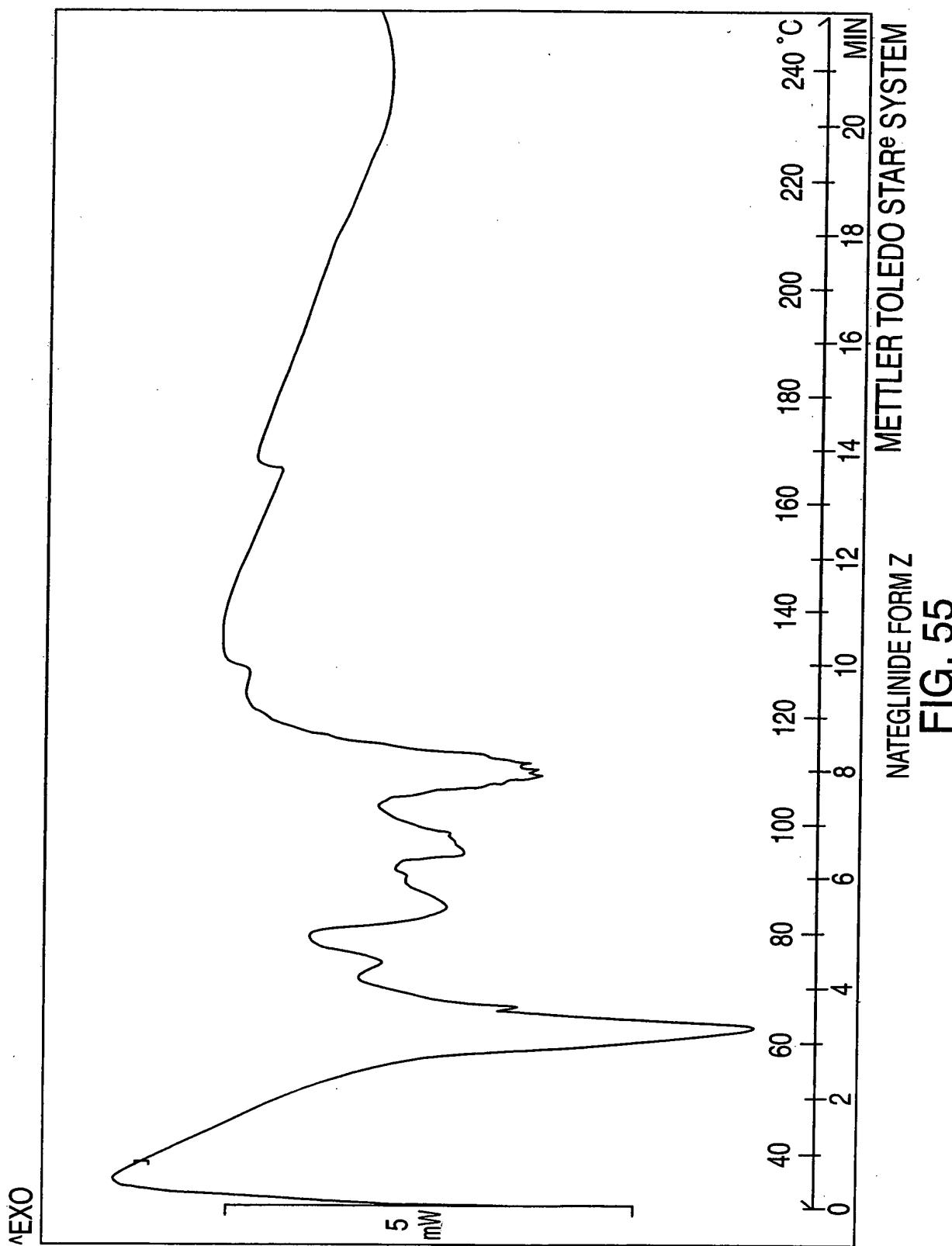
FIG. 51  
FORM U

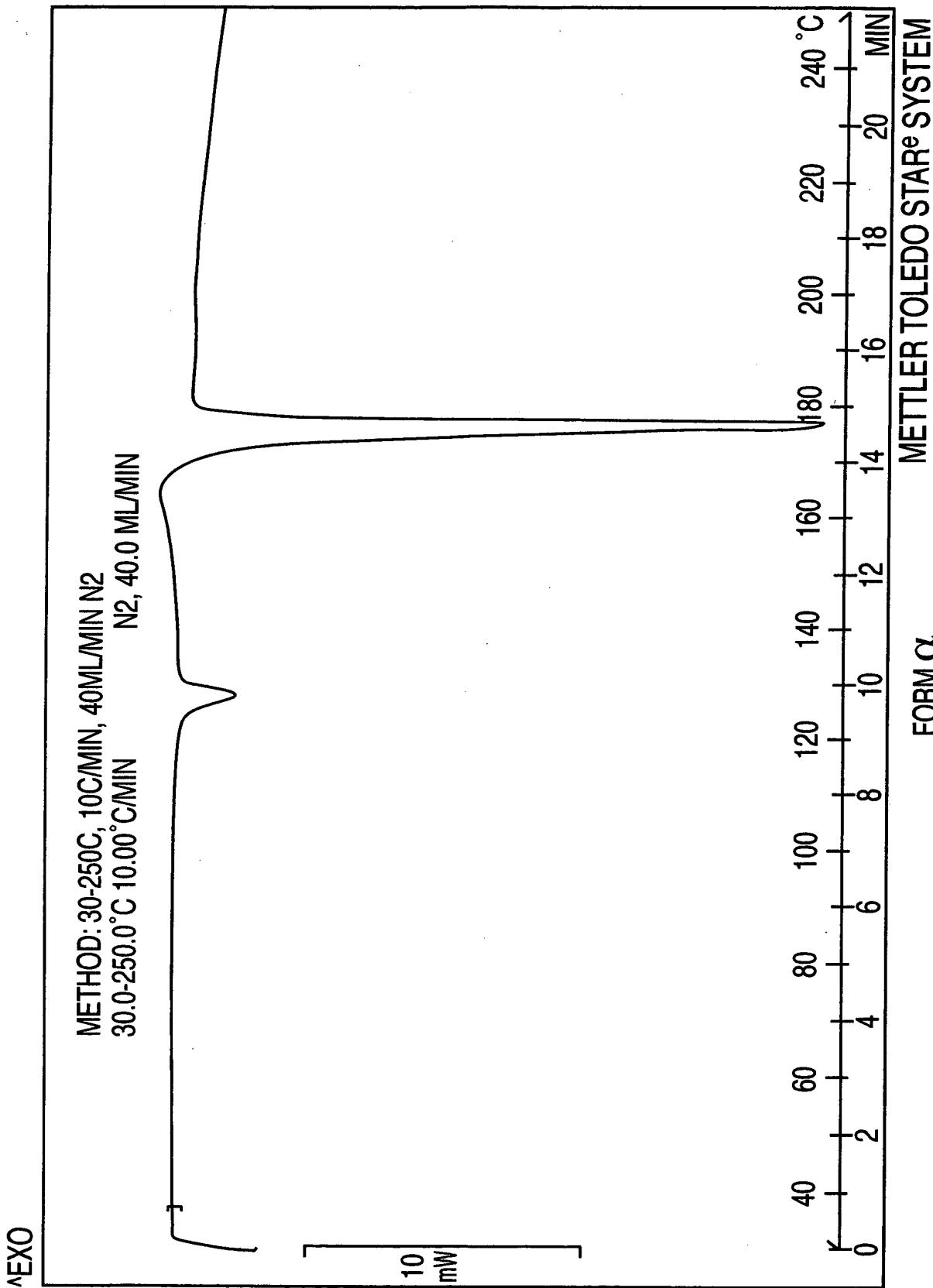


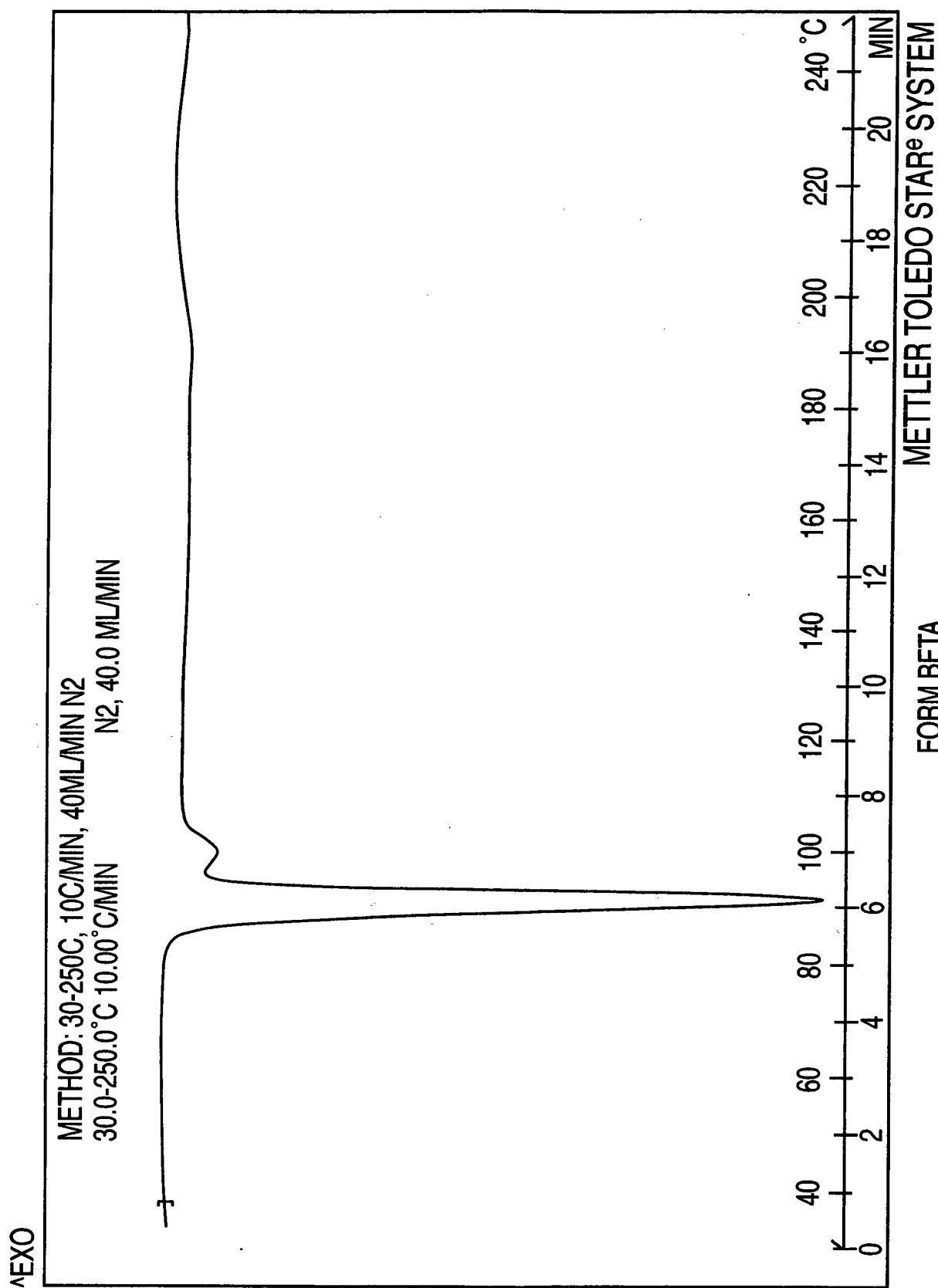


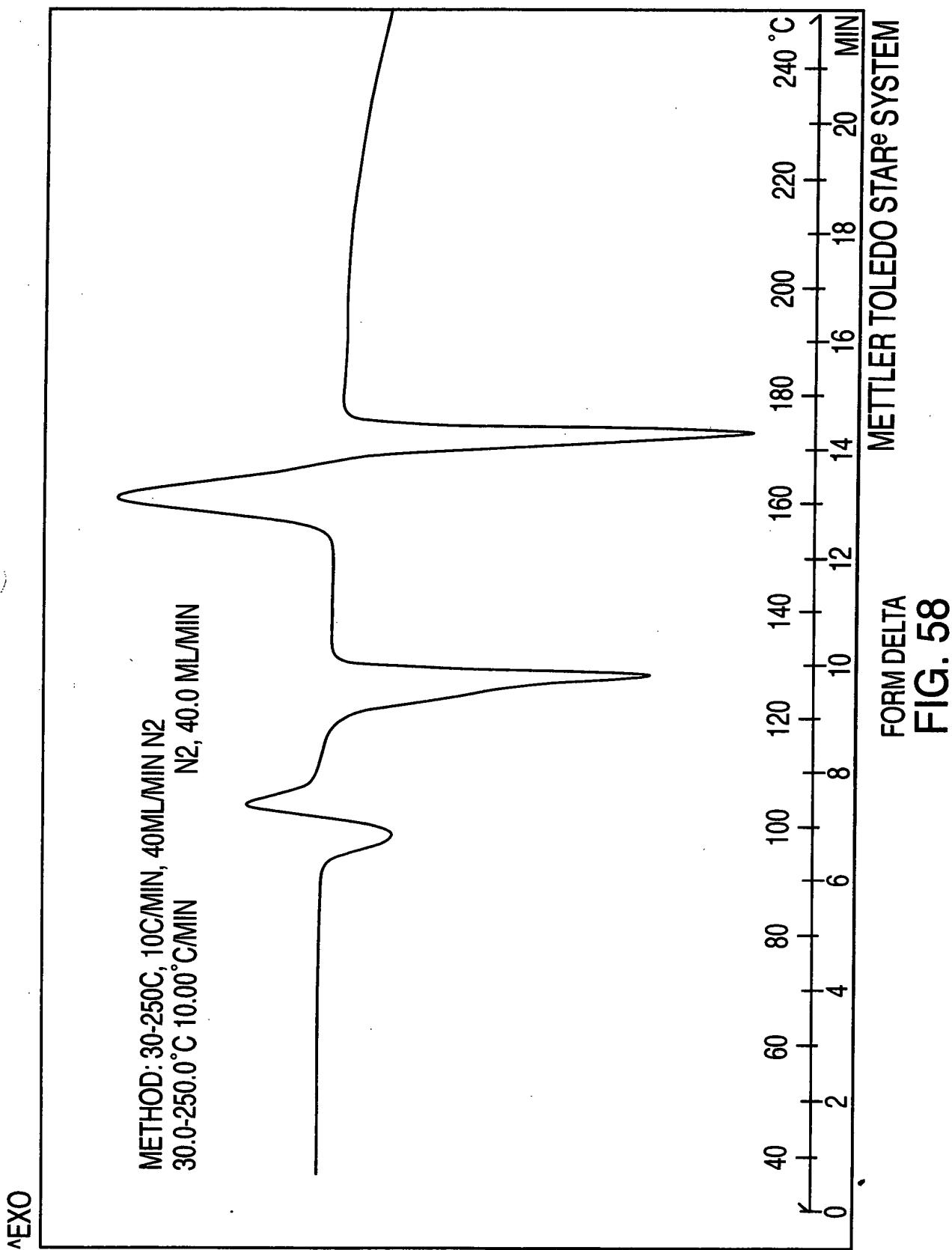


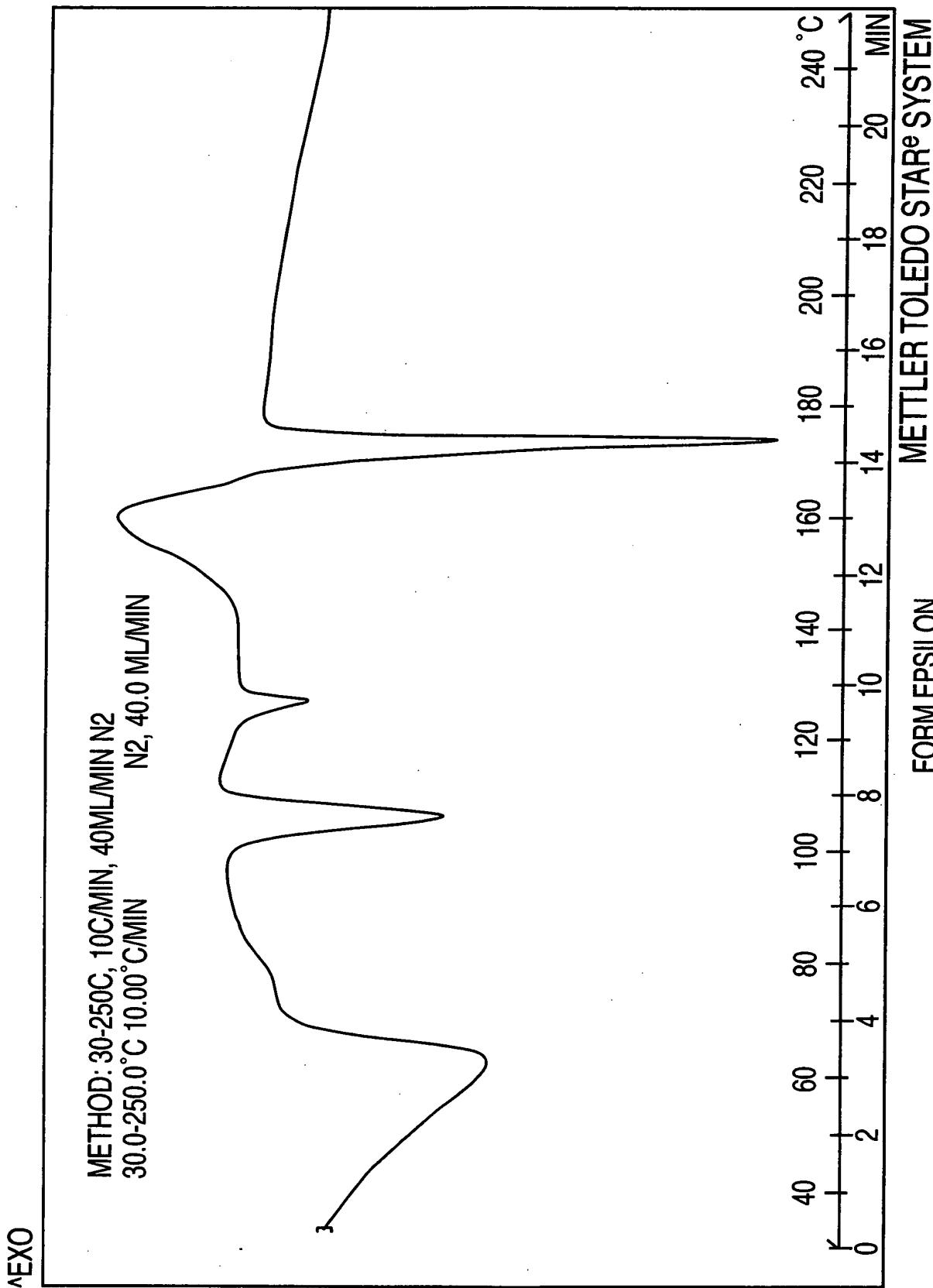
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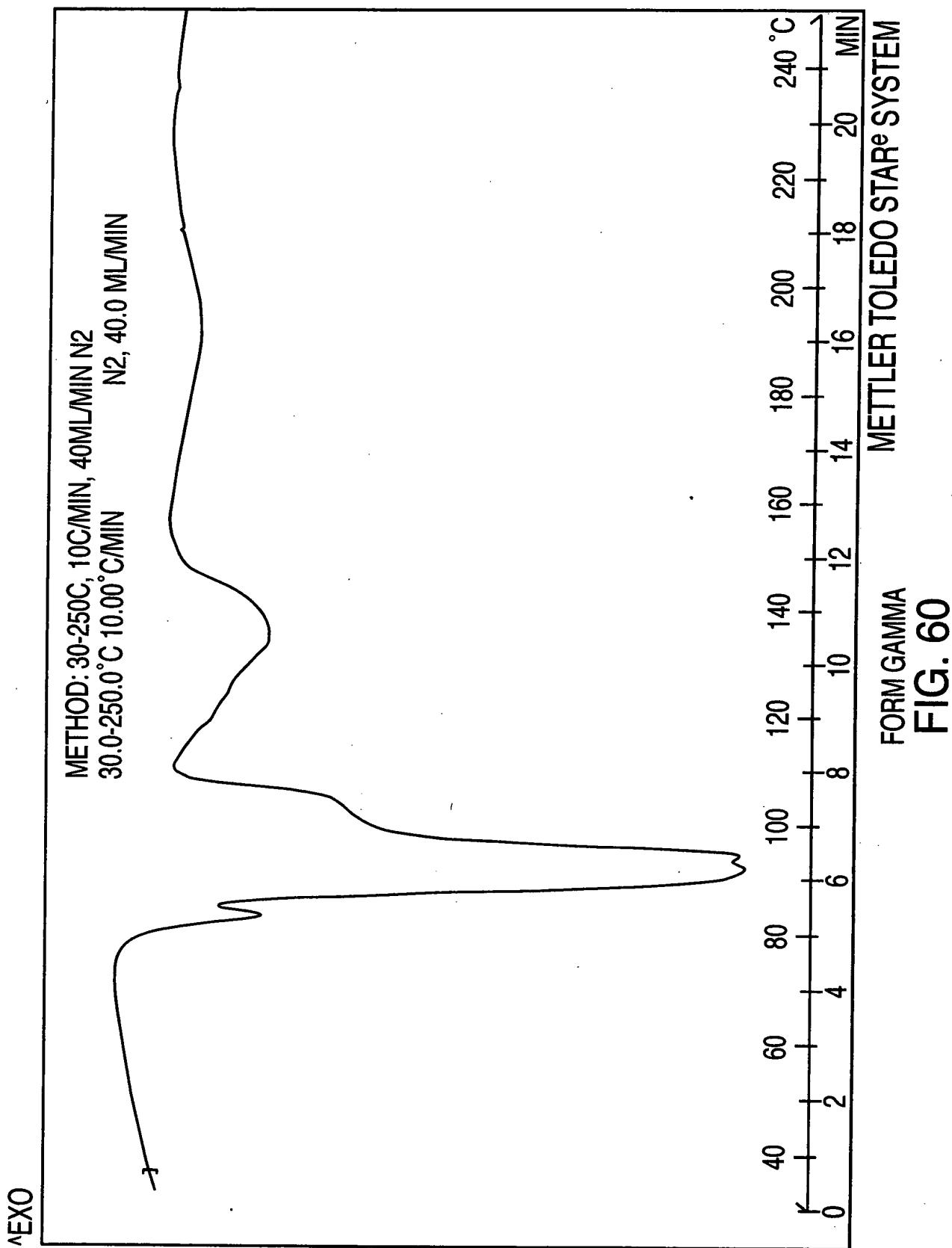


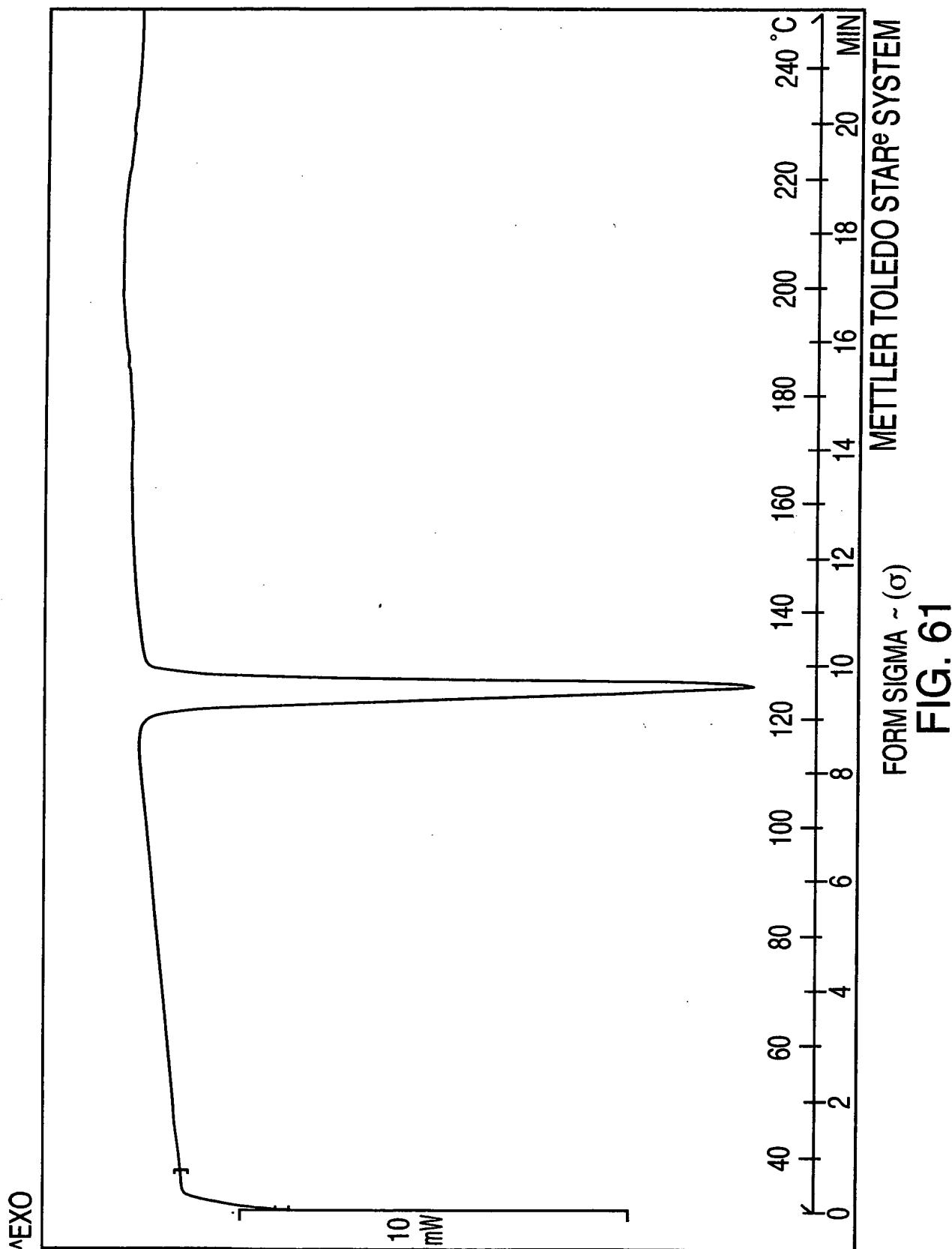


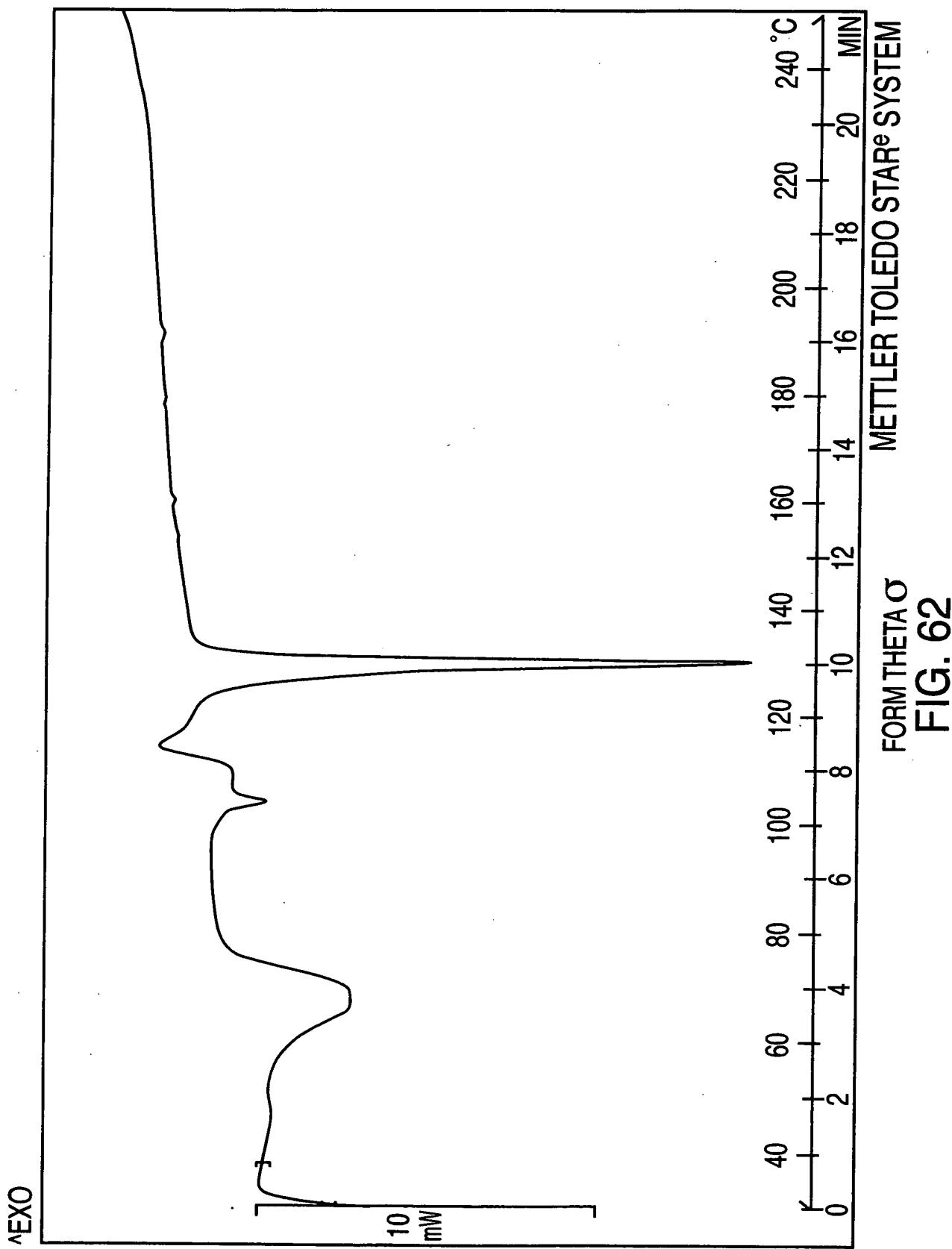




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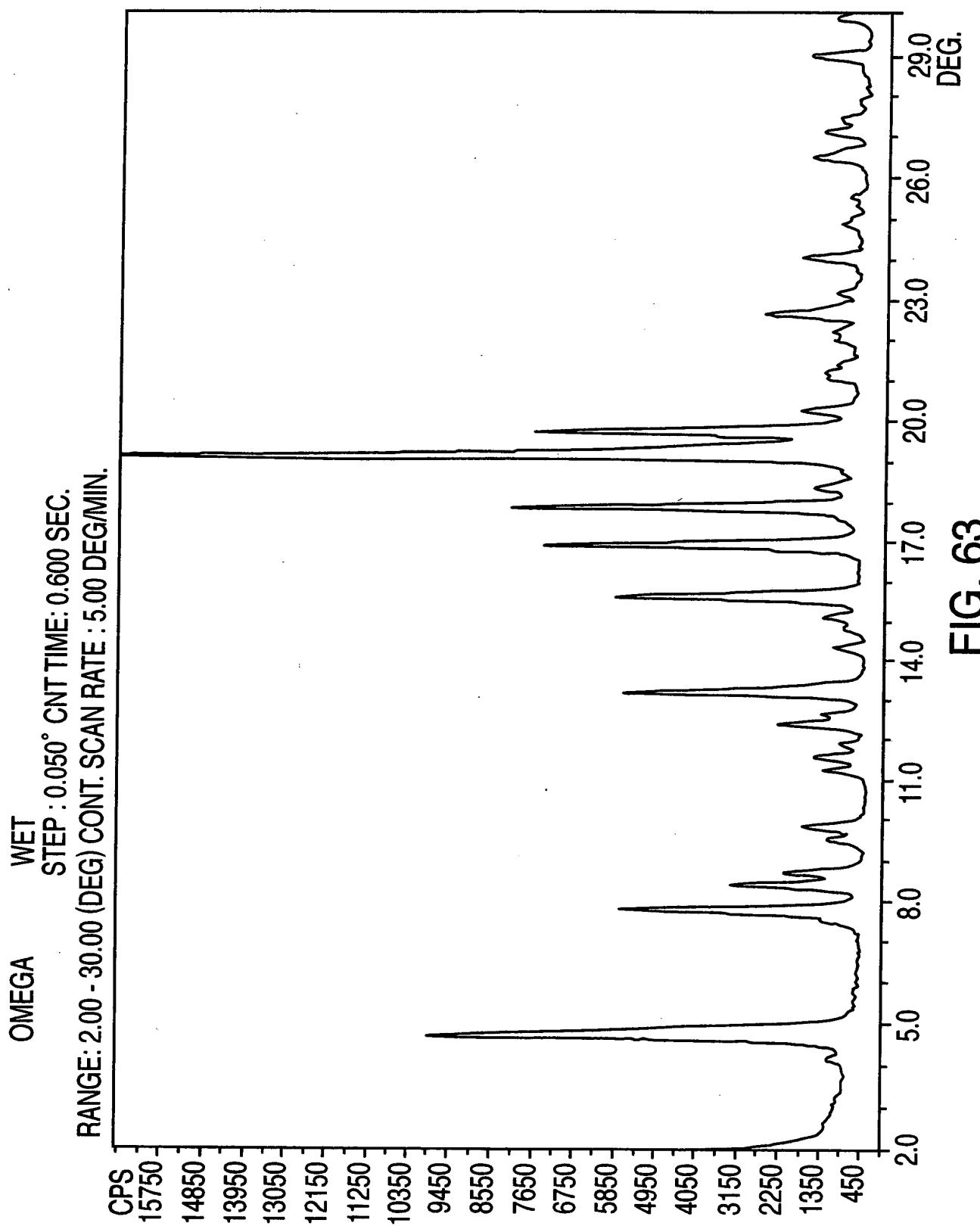


FIG. 63

Comparison between the impurity profile of Nateglinide crystallized in IPA-H<sub>2</sub>O and Nateglinide in Methanol-H<sub>2</sub>O

Sample No	Solvent	Impurity profile by RRT [% w/w]							
		D-PA (0.23)	(0.25) (0.46)	(0.80)	Ipcha (0.89)	Dimer (1.38)	Methyl Ester (1.51)	Isopropyl Ester (1.76)	Isopropyl Ester (2.3)
RL-2155/1	Methanol-H <sub>2</sub> O	<0.01		0.02	<0.01	0.03	0.02	2.91	0.04
RL-2163/4	IPA-H <sub>2</sub> O	<0.01	0.04	0.02	0.02	0.01		0.03	0.02

Note: D-PA means D-Phenyl Alanine

Ipcha means Iso propyl cyclohexyl carboxylic acid

Both are the starting materials of the product

(-)N-[(trans-4-isopropyl cyclohexane)carbonyl]-D-phenylalanine

FIG. 64